

EXHIBIT A

**Transcript of Deposition of Patrick Kelly,
Volume 1 – 05/10/2019**

Kelly, Patrick

Volume 1 - 05/10/2019

Condensed Proceeding with Highlighted Clips

Printed 10/16/2020 12:10PM CDT

CONFIDENTIAL



Plaintiff Initial

00001
01: IN THE UNITED STATES DISTRICT COURT
02: FOR THE NORTHERN DISTRICT OF OHIO
03: EASTERN DIVISION
04: - - -
05:
IN RE: NATIONAL : HON. DAN A.
06: PRESCRIPTION OPIATE : POLSTER
LITIGATION :
07: :
APPLIES TO ALL CASES : NO.
08: : 1:17-MD-2804
:
09:
- HIGHLY CONFIDENTIAL -
10:
SUBJECT TO FURTHER CONFIDENTIALITY REVIEW
11:
- - -
12:
May 10, 2019
13:
- - -
14:
15: Videotaped deposition of
PATRICK KELLY, taken pursuant to notice,
16: was held at the offices of Baron & Budd,
600 New Hampshire Avenue, NW, Washington,
17: D.C., beginning at 8:58 a.m., on the
above date, before Michelle L. Gray, a
18: Registered Professional Reporter,
Certified Shorthand Reporter, Certified
19: Realtime Reporter, and Notary Public.

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20: - - -
21:
GOLKOW LITIGATION SERVICES
22: 877.370.3377 ph | 917.591.5672 fax
deps@golkow.com
23:
24:

p. 00001a

00002
01: APPEARANCES:
02:
BARON & BUDD, P.C.
03: BY: MARK P. PIFKO, ESQ.
BY: STERLING CLUFF, ESQ.
04: Encino Plaza
15910 Ventura Boulevard
05: Suite 1600
Encino, California 91436
06: (818) 839-2333
mpifko@baronbudd.com
07: scluff@baronbudd.com
Representing the Plaintiffs
08:
09: BRANSTETTER, STRANCH & JENNINGS, PLLC
BY: MICHAEL G. STEWART, ESQ.
10: 223 Rosa L. Parks Avenue
Suite 200
11: Nashville, Tennessee 37203
(615) 254-8801
12: mstewart@bsjfirm.com
Representing the Tennessee Plaintiffs
13:
14: DAVIS POLK & WARDWELL, LLP
BY: BRIAN S. WEINSTEIN, ESQ.
15: BY: MEREDITH MANNING, ESQ.
450 Lexington Avenue
16: New York, New York 10017
(212) 450-3037
17: brian.weinstein@davispolk.com
Meredith.manning@davispolk.com
18: Representing HDA and the Witness

p. 00002

19:
BARNES & THORNBURG, LLP
20: BY: WILLIAM E. PADGETT, ESQ.
11 South Meridian Street
21: Indianapolis, Indiana 46204
(317) 236-1313
22: william.padgett@btlaw.com
Representing the Defendant, H.D. Smith
23:
24:

p. 00002a

00003
01: APPEARANCES: (Cont'd.)
02:
DECHERT, LLP
03: BY: MELANIE MACKAY, ESQ.
35 West Wacker Drive
04: Suite 3400
Chicago, Illinois 60601
05: (312) 646-5800
melanie.mackay@dechert.com
06:
- and -
07:
DECHERT, LLP
08: BY: DANA MARTIN, ESQ.
35 West Wacker Drive
09: Suite 3400
Chicago, Illinois 60601
10: (312) 646-5800
dana.martin@dechert.com
11: Representing the Defendant, Purdue
Pharmaceuticals
12:
13: REED SMITH, LLP
BY: ANNE E. ROLLINS, ESQ.
14: Three Logan Square
1717 Arch Street, Suite 3100
15: Philadelphia, Pennsylvania 19103
(215) 851-8226
16: arollins@reedsmith.com
Representing the Defendant,
17: AmerisourceBergen Drug Corporation
18:

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WILLIAMS & CONNOLLY, LLP
19: BY: JENNIFER G. WICHT, ESQ.
BY: KATELYN ADAMS, ESQ.
20: 725 12th Street, NW
Washington, D.C. 20005
21: (202) 434-5148
jwicht@wc.com
22: kadams@wc.com
Representing the Defendant, Cardinal
23: Health
24:

p. 00003a

00004
01: APPEARANCES: (Cont'd.)
02:
ZUCKERMAN SPAEDER, LLP
03: BY: KYLE A. CRAWFORD, ESQ.
1800 M Street, NW
04: Suite 1000
Washington, D.C. 20036
05: (202) 778-1825
kcrawford@zuckerman.com
06: Representing the Defendant, CVS
07:
JONES DAY
08: BY: SERGIO A. TOSTADO, ESQ.
325 John H. McConnell Boulevard
09: Suite 600
Columbus, Ohio 43215
10: (614) 281-3898
stostado@jonesday.com
11: Representing the Defendant, Walmart
12:
COVINGTON & BURLING, LLP
13: BY: AMBER M. CHARLES, ESQ.
850 Tenth Street, NW
14: Suite 586N
Washington, D.C. 20001
15: (202) 662-5613
acharles@cov.com
16: Representing the Defendant, McKesson
Corporation
17:
18: MARCUS & SHAPIRA, LLP
BY: ELLY HELLER-TOIG, ESQ.

p. 00004

19: One Oxford Centre, 35th Floor
Pittsburgh, Pennsylvania 15219
20: (412) 338-3990
ehtoig@marcus-shapira.com
21: Representing the Defendant, HBC
Service Company
22:
23:
24:

p. 00004a

00005
01: APPEARANCES: (Cont'd.)
02:
ARNOLD PORTER KAYE SCHOLER, LLP
03: BY: WREDE SMITH, ESQ.
601 Massachusetts Avenue, NW
04: Washington, D.C. 20001
(202) 942-5000
05: wrede.smith@arnoldporter.com
Representing the Defendants, Endo Health
06: Solutions Endo Pharmaceuticals, Inc.; Par
Pharmaceutical Companies, Inc. f/k/a Par
07: Pharmaceutical Holdings, Inc.
08:
09:
10:
11:
12:
13:
14:
15:
16:
17:
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19:
20:
21:
22:
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24:

p. 00005

18: asherman@baronbudd.com
Representing the Plaintiffs
19:
20: TUCKER ELLIS, LLP
BY: ANDREA M. GLINKA PRZYBYSZ, ESQ.
21: 233 S. Wacker Drive, Suite 6950
Chicago, Illinois 60606
22: (312) 624-6322
andrea.przybysz@tuckerellis.com
23: Representing the Defendant, Janssen and
Johnson & Johnson
24:

p. 00006a

00006
01: TELEPHONIC/STREAMING APPEARANCES:
02:
03: GREENE KETCHUM FARRELL BAILEY & TWEEL, LLP
PAUL T. FARRELL, JR., ESQ.
04: 419 Eleventh Street
Huntington, West Virginia 25701
05: (304) 521-4778
Paul@greeneketchum.com
06:
- and -
07:
BARON & BUDD, P.C.
08: BY: WILLIAM G. POWERS, ESQ.
600 New Hampshire Avenue, NW
09: The Watergate, Suite 10-A
Washington, D.C. 20037
10: (202) 333-4562
Wpowers@baronbudd.com
11:
- and -
12:
BARON & BUDD, P.C.
13: BY: JAY LICHTER, ESQ.
BY: JEFFREY LIPINSKI, ESQ.
14: BY: ALEX SHERMAN, ESQ.
Encino Plaza
15: 15910 Ventura Boulevard
Suite 1600
16: Encino, California 91436
(818) 839-2333
17: jlichter@baronbudd.com
jlipinski@baronbudd.com

p. 00006

00007
01: TELEPHONIC/STREAMING APPEARANCES:
(Cont'd.)
02:
03: FOLEY & LARDNER, LLP
BY: GREGORY N. HEINEN, ESQ.
04: 777 East Wisconsin Avenue
Milwaukee, Wisconsin 53202
05: (414) 297-5913
Gheinen@foley.com
06: Representing Anda Inc.
07:
08:
09:
LOCKE LORD, LLP
10: BY: MADELEINE E. BRUNNER, ESQ.
2200 Ross Avenue
11: Suite 2800
Dallas, Texas 75201
12: (214) 740.8758
Maddie.brunner@lockelord.com
13: Representing the Defendant,
Henry Schein, Inc.
14:
15: BAILEY WYANT PLLC
BY: HARRISON M. CYRUS, ESQ.
16: 500 Virginia Street East
Suite 600
17: Charleston, West Virginia 25301
(304) 345-4222
18: Hcyrus@baileywyant.com
Representing the Defendant, West
19: Virginia Board of Pharmacy

p. 00007

20:
21: BARTLIT BECK, LLP
BY: LESTER C. HOUTZ, ESQ.
22: 1801 Wewatta Street, Suite 1200
Denver, Colorado 80202
23: (303) 592-3199
lester.houtz@bartlit-beck.com
24: Representing the Defendant, Walgreens

19:
20:
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22:
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24:

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00008
01: TELEPHONIC/STREAMING APPEARANCES:
(Cont'd.)
02:
03:
FOX ROTHSCHILD, LLP
04: BY: ZACHARY MARTIN, ESQ.
2700 Kelly Road
05: Suite 300
Warrington, Pennsylvania 18976
06: (215) 918-3680
Zmartin@foxrothschild.com
07: Representing the Defendant, Prescription
Supply Inc.
08:
09: ROPES & GRAY LLP
BY: GREGORY MALLOY, ESQ.
10: 800 Boylston Street
Boston, Massachusetts 02199
11: (617) 951-7234
Gregory.malloy@ropesgray.com
12: Representing the Defendant,
Mallinckrodt
13:
14: TUCKER ELLIS, LLP
BY: JEFFREY M. WHITESELL, ESQ.
15: 950 Main Avenue
Suite 1100
16: Cleveland, Ohio 44113
(216) 696-2286
17: Jeffrey.whitesell@tuckerellis.com
Representing the Defendant, Janssen and
18: Johnson & Johnson

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00009
01: APPEARANCES: (Cont'd.)
02:
03: ALSO PRESENT:
04:
Elizabeth A. Gallenagh, Esq.
05: (HDA)
06:
VIDEO TECHNICIAN:
07: Dan Holmstock
08:
LITIGATION TECHNICIAN:
09: James Beall
10:
11:
12:
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00010
01: - - -
02: I N D E X
03: - - -
04:
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05: PATRICK KELLY
06:
By Mr. Pifko 26
07:
By Ms. MacKay 438
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11:
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14: NO. DESCRIPTION PAGE
15: HDA
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16: Notice of Subpoena
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17:
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18: Kelly-2 E-mail, 10/31/16 35
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19: Of HDMA DEA
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20: 10/31/16
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21: HDA_MDL_000081363-76
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02: E X H I B I T S (Cont'd.)
03: - - -
04:
05: NO. DESCRIPTION PAGE
06: HDA
Kelly-3 E-mail Thread 50
07: 5/30/07
Subject, Confirmed
08: HDMA Conference Call
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09: His-MDL-00620224-29
10: HDA
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11: 9/26/07
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12: Strategy Meeting
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13: CAH_MDL_PRIORPROD_DEA07
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15: Kelly-5 E-mail Thread 66
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16: Subject, HDMA Board
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17: HDA_MDL_000213427
18: HDA
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05: NO. DESCRIPTION PAGE
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21: Subject, Suspicious
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22: HDA_MDL_000150198
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01: - - -
02: E X H I B I T S (Cont'd.)
03: - - -
04:
05: NO. DESCRIPTION PAGE
06: HDA
Kelly-13 E-mail Thread 122
07: 1/17/08
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08: HDA_MDL_000139414-15
09: HDA
Kelly-14 E-mail Thread 131
10: 2/6/08
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11: Conference Call
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13: HDA
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15: And Anti-Harassment
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16: HDA_MDL_000213212-28
17: HDA
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19: Prevention
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20: Arlington VA
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21:
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23: HDA_MDL_000141125-33
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02: E X H I B I T S (Cont'd.)
03: - - -
04:
05: NO. DESCRIPTION PAGE
06: HDA
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07: Subject, Discussion
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08: HDA_MDL_000217851-53
09: HDA
Kelly-19 E-mail Thread 186
10: 2/6/08
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11: Conference Call Reminder
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13: Kelly-20 HDMA DEA Suspicious 199
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14: Best Practices
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16:
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17: Kelly-21 E-mail Thread 210
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18: Subject, HDMA RAC
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19: CAH_MDL2804_01521412-69
20: HDA

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Kelly-22 E-mail Thread 215
21: 3/20/08
Subject, DEA Strategy
22: Document and
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23: Anda_Opioids_MDL_
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24:

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00015
01: - - -
02: E X H I B I T S (Cont'd.)
03: - - -
04:
05: NO. DESCRIPTION PAGE
06: HDA
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07: DEA-HDMA Meeting
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08: CAH_MDL2804_
02489188-90
09:
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10: Kelly-24 E-mail Thread 242
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11: Subject, RAC
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12: HDA_MDL_000156499-01
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20: CAH_MDL2804_02489191-96
21: HDA
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02: E X H I B I T S (Cont'd.)
03: - - -
04:
05: NO. DESCRIPTION PAGE
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07: To Gray from Goggin
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09: Kelly-29 Slide Deck Webinar 287
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10: Guidelines: Reporting
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14: Kelly-30 E-mail Thread 294
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15: Subject, For Review
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16: One Pager
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17:
HDA
18: Kelly-31 Chronology of 299
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19: Committee and

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Board of Directors'
20: Drug Abuse
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21: HDA_MDL_000155930-47
22:
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24:

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00017
01: - - -
02: E X H I B I T S (Cont'd.)
03: - - -
04:
05: NO. DESCRIPTION PAGE
06: HDA
Kelly-32 E-mail Thread 302
07: 10/1/13
Subject, HDMA - Review
08: Requested by Thursday
10/3 12 Noon Eastern
09: HDA_MDL_000081415-16
10: HDA
Kelly-33 GAO Meeting on DEA 303
11: Draft TPs 9/20/10
HDA_MDL_000139905-10
12:
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13: Kelly-34 E-mail Thread 314
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14: Subject, DEA
Initiatives
15: HDA_MDL_000215234-36
16: HDA
Kelly-35 E-mail Thread 331
17: 12/19/13
Subject, Follow-up
18: HDMA Drug Diversion
Task Force
19: Meeting 12/11/13
CAH_MDL2804_01110712-15
20:

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21:
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01: - - -
02: E X H I B I T S (Cont'd.)
03: - - -
04:
05: NO. DESCRIPTION PAGE
06: HDA
Kelly-36 E-mail Thread 347
07: 9/22/14
Subject, Manufacturer
08: Issue with Imminent
Danger Definition
09: HDA_MDL_000214864-65
10: HDA
Kelly-37 E-mail Thread 351
11: 1/15/15
Subject, Reintroduction
12: Of Ensuring Patient
Access and Effective
13: Drug Enforcement Act
HDA_MDL_000081283-84
14:
HDA
15: Kelly-38 E-mail Thread 354
3/5/15
16: Subject, Final Letter
Of Support for Ensuring
17: Patient Access and
Effective Drug Enforcement
18: Act of 2015
HDA_MDL_000081651-54
19:
HDA

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20: Kelly-39 Statement from John 355
M. Gray, President and
21: CEO HDMA
4/7/14
22:
23:
24:

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00019
01: - - -
02: E X H I B I T S (Cont'd.)
03: - - -
04:
05: NO. DESCRIPTION PAGE
06: HDA
Kelly-40 E-mail Thread 360
07: 3/24/14
Subject, Coordination
08: Call Today?
MCKMDL00651560-64
09:
HDA
10: Kelly-41 E-mail Thread 370
5/1/17
11: Subject, HDA Letters
Supportive of Opioid
12: Approaches in the States
HDA_MDL_000214979-82
13:
HDA
14: Kelly-42 E-mail Thread 375
8/5/08
15: Subject, HDMA RAC
Conference Call
16: Reminder
CAH_MDL2804_01364288-300
17:
HDA
18: Kelly-43 E-mail Thread 382
2/9/12
19: Subject, New DEA

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TPs
20: HDA_MDL_00088099-01
21: HDA
Kelly-44 E-mail Thread 389
22: 2/23/12
Subject, Draft Amicus
23: Brief Cardinal v Holder
HDA_MDL_000215212-33
24:

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00020
01: - - -
02: E X H I B I T S (Cont'd.)
03: - - -
04:
05: NO. DESCRIPTION PAGE
06: HDA
Kelly-45 E-mail Thread 393
07: 2/27/12
Subject, Cardinal's
08: Counsel's Comments
On Amicus Brief
09: HDL_MDL_000215970-73
10: HDA
Kelly-46 E-mail Thread 398
11: 3/5/12
Subject, HDMA Amicus
12: Brief Cardinal v Holder
HDA_MDL_000216300-02
13:
HDA
14: Kelly-47 E-mail Thread 404
11/19/15
15: Subject, Masters Suit
Draft Amicus Outline
16: For Your Consideration
HDA_MDL_000219211-13
17:
HDA
18: Kelly-48 E-mail Thread 406
1/18/16
19: Subject, Action Requested
HDMA/Masters Amicus Brief

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20: HDA_MDL_000215966-67
21: HDA
Kelly-49 E-mail Thread 408
22: 4/5/16
Subject, Amicus Brief
23: Files in Masters Case
HDA_MDL_000162206-56
24:

p. 00020a

00021
01: - - -
02: E X H I B I T S (Cont'd.)
03: - - -
04:
05: NO. DESCRIPTION PAGE
06: HDA
Kelly-50 E-mail Thread 412
07: 10/29/15
Subject, HDMA Amicus
08: Brief
HDA_MDL_000212579-16
09:
HDA
10: Kelly-51 Letter, 4/27/84 420
To Streck from Gitchel
11: CAH_MDL2804_02201918-20
12:
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p. 00021

00022
01: - - -
02: DEPOSITION SUPPORT INDEX
03: - - -
04:
05: Direction to Witness Not to Answer
06: PAGE LINE
None.
07:
08: Request for Production of Documents
09: PAGE LINE
30 18
10:
11: Stipulations
12: PAGE LINE
None.
13:
14: Questions Marked
15: PAGE LINE
429 4
16:
17:
18:
19:
20:
21:
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Page 10

00023

01: - - -
02: THE VIDEOGRAPHER: We are
03: now on the record. My name is
04: Daniel Holmstock. I'm the
05: videographer for Golkow Litigation
06: Services.
07: Today's date is May 10,
08: 2019. The time on the video
09: screen is 8:58 a.m.
10: This deposition is being
11: held at the law offices of Baron &
12: Budd at 600 New Hampshire Avenue
13: Northwest, in Washington DC, in
14: the matter of In Re National
15: Prescription Opiate Litigation,
16: pending before the United States
17: District Court for the Northern
18: District of Ohio, Eastern
19: Division, MDL No. 2804.
20: Our deponent today is
21: Mr. Patrick Kelly, testifying in
22: his individual and 30(b)(6)
23: capacity for Healthcare
24: Distribution Alliance.

p. 00023

00025

01: MR. WEINSTEIN: Brian
02: Weinstein from Davis Polk for HDA
03: and the witness.
04: MS. MANNING: Meredith
05: Manning from Davis Polk for HDA
06: and the witness.
07: MS. GALLENGAGH: Liz
08: Gallenagh, general counsel for
09: HDA.
10: MR. TOSTADO: Sergio
11: Tostado, Jones Day, for Walmart.
12: MR. CRAWFORD: Kyle
13: Crawford, Zuckerman Spaeder, for
14: the CVS defendants.
15: MS. WICHT: Jennifer Wicht,
16: Williams & Connolly, Cardinal
17: Health.
18: MS. ADAMS: Katelyn Adams,
19: Williams & Connolly, Cardinal
20: Health.
21: MR. PADGETT: Bill Padgett,
22: Barns & Thornburg for HD Smith.
23: MS. ROLLINS: Anne Rollins,
24: Reed Smith, for AmerisourceBergen

p. 00025

00024

01: Counsel for appearances will
02: be noted on the stenographic
03: record.
04: The court reporter is
05: Michelle Gray who will now
06: administer the oath to the
07: witness.
08: - - -
09: ...PATRICK KELLY, having
10: been first duly sworn, was
11: examined and testified as follows:
12: - - -
13: MR. PIFKO: Can we just go
14: around the room so I know who
15: everyone is who's here. I know
16: we're going to keep -- the
17: reporter said everything would be
18: noted on the record.
19: But if everyone can
20: introduce yourself, your firm, and
21: who you represent.
22: So I'm Mark Pifko from Baron
23: & Budd on behalf of the
24: plaintiffs' executive committee.

p. 00024

00026

01: Drug Incorporation.
02: MS. HELLER-TOIG: Elly
03: Heller-Toig from Marcus & Shapiro
04: for HBC Service Company.
05: MR. SMITH: Wrede Smith from
06: Arnold & Porter for the Endo/Par
07: defendants.
08: MR. STEWART: Mike Stewart,
09: Branstetter, Stranch & Jennings,
10: for the Tennessee case.
11: MS. CHARLES: Amber Charles,
12: Covington & Burling, for McKesson
13: Corporation.
14: MS. MARTIN: Dana Martin,
15: Dechert, for Purdue.
16: MS. MACKAY: Melanie MacKay
17: from Dechert for Purdue.
18: MR. CLUFF: Sterling Cluff,
19: Baron & Budd.
20: - - -
21: EXAMINATION
22: - - -
23: BY MR. PIFKO:
24: Q. All right, Mr. Kelly. My

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01: name is Mark Pifko, as you just heard.
02: We just met for the first time off the
03: record. I'm going to be asking you some
04: questions today.
05: I'm want to go over some
06: basic things before we get started.
07: A. Yeah.
08: Q. First and foremost, you are
09: under oath. So you understand that your
10: testimony here is under penalty of
11: perjury, right?
12: A. I do.
13: Q. Okay. And that means that
14: you're sworn to tell the truth, and if
15: you are intentionally misleading or
16: dishonest, you could be subject to
17: penalties from the court. Do you
18: understand that?
19: A. I understand.
20: Q. Is there any reason why
21: you're not able to give truthful and
22: accurate testimony today?
23: A. No.
24: Q. You've been deposed before,

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00028

01: correct?
02: A. Yes.
03: Q. How many times have you been
04: deposed before?
05: A. Once.
06: MS. MACKAY: Mark, I'm sorry
07: to interrupt. Can we just get on
08: the record that an objection from
09: one attorney is good for all?
10: MR. PIFKO: Yeah, that's
11: actually part of the depo
12: protocol, so we're good on that.
13: MS. MACKAY: Great, thank
14: you.
15: BY MR. PIFKO:
16: Q. So, okay, you've been
17: deposed one time before?
18: A. Correct.
19: Q. So --
20: MR. HOUTZ: This is Lester
21: Houtz on the phone from Bartlit
22: Beck for Walgreens. And I'm
23: hearing the questions fine. But I
24: cannot hear the answers at all.

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01: THE VIDEOGRAPHER: The only
02: way to do that is to speak up.
03: THE WITNESS: I can speak
04: up. I'll speak up.
05: BY MR. PIFKO:
06: Q. All right. So there's no
07: reason why you can think of that your
08: deposition shouldn't proceed today?
09: A. No.
10: Q. Is there any reason why you
11: wouldn't be able to give truthful and
12: accurate testimony today?
13: A. No.
14: Q. All right. I've got some
15: materials here. I think for the most
16: part I'm going to ask you to confirm some
17: information. So as long as you're
18: truthful and honest, I think that it is
19: going to be an easy day for you.
20: You said that you were
21: deposed one other time?
22: A. Yes.
23: Q. What -- what was that?
24: A. We were deposed in the

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01: Montana litigation.
02: Q. Okay. Was that -- you were
03: deposed in connection with your role for
04: the HDA?
05: A. Correct.
06: Q. And when was that?
07: A. September. I forget the
08: exact date.
09: Q. Okay. Where did that
10: happen? Was that here in DC?
11: A. Here in Washington DC.
12: Q. Okay. Was there a
13: transcript of that?
14: A. I imagine there was.
15: Q. Okay. Have you seen the
16: transcript?
17: A. I have not.
18: MR. PIFKO: Okay. We're
19: going to request a copy of that
20: just for potential impeachment
21: purposes.
22: MR. WEINSTEIN: We can talk
23: about that offline.
24: MR. PIFKO: Okay.

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00031
01: BY MR. PIFKO:
02: Q. All right. So you
03: understand that you're here to answer
04: questions and your counsel may object
05: from time to time. But unless he
06: instructs you not to answer, you're still
07: going to answer the question.
08: Understood?
09: A. Understood.
10: Q. Okay. So you understand
11: that you're here in your individual
12: capacity but you're also here as the
13: official representative of HDA with
14: respect to certain topics, correct?
15: A. I understand that, yes.
16: Q. Okay. And so that means
17: when you answer within those topics,
18: you're answering as if you are the HDA.
19: Do you understand that?
20: A. I understand that.
21: Q. Okay. I'm going to hand you
22: a copy of the notice.
23: (Document marked for
24: identification as Exhibit

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00033
01: Q. And I want to turn your
02: attention to -- there's some definitions
03: in the notice, if you can flip a few
04: pages in. My -- after you get through
05: some of the initial pages, it's marked
06: Page 3.
07: A. Okay.
08: Q. Are you there?
09: A. I am.
10: Q. It says, "The terms 'you,'
11: 'your,' and 'HDA.'"
12: Do you see that under D?
13: A. I do.
14: Q. Okay. That refers to HDA
15: and its predecessor organizations
16: including the Healthcare Distribution
17: Management Association and the National
18: Wholesale Druggists' Association, the
19: Western Wholesale Druggists' Association.
20: Do you see that?
21: A. I do.
22: Q. And you understand that when
23: I ask you questions today about you, I'm
24: referring to those entities, okay?

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00032
01: HDA-Kelly-1.)
02: BY MR. PIFKO:
03: Q. I'm handing you what's
04: marked as Exhibit 1, which is a copy of
05: the notice that brought us here today.
06: Have you seen this before?
07: A. I have.
08: Q. When was the first time you
09: saw this?
10: A. Received it yesterday or the
11: day before in preparation for this.
12: Q. Okay. You are aware that
13: there's topics for which you're
14: designated?
15: A. Yes.
16: Q. When was the first time that
17: you became aware of the topics for which
18: you're designated?
19: A. Two days ago in preparation
20: for this.
21: Q. So the first time that you
22: had seen any of these topics was two days
23: ago?
24: A. Yes.

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01: A. Yes.
02: MR. WEINSTEIN: Mark, I just
03: ask if there are times that you're
04: asking him in his personal
05: capacity, when you say you, if you
06: can make that clear, that would be
07: great.
08: MR. PIFKO: I think most of
09: the questions today will be
10: 30(b)(6).
11: BY MR. PIFKO:
12: Q. Okay. So I want to then
13: turn your page -- or turn your attention
14: a few pages in to the topics. They start
15: on Page 5.
16: Do you see that?
17: A. I do.
18: Q. Okay. Go to Topic 4, which
19: actually is on Page 6.
20: Do you see Topic 4?
21: A. I do.
22: Q. Okay. It's about the
23: industry compliance guidelines, including
24: the development of the guidelines,

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01: communications regarding the guidelines
02: and modifications, revisions or changes
03: to the guidelines, and any councils,
04: committee, task force or working groups
05: concerning the guidelines.
06: Do you see that?
07: A. I do.
08: Q. Are you prepared to provide
09: testimony on that topic today?
10: A. To the best -- to the best
11: of my ability, yes.
12: Q. Okay.
13: MR. CRAWFORD: Go ahead on
14: the phone again.
15: (Brief interruption.)
16: (Document marked for
17: identification as Exhibit
18: HDA-Kelly-2.)
19: BY MR. PIFKO:
20: Q. All right. I'm handing you
21: what's been marked as Exhibit 2, which is
22: a document Bates-labeled
23: HDA_MDL_000081363 to 81376. Have you
24: seen this before?

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01: A. I have.
02: Q. Okay. This is a document
03: from Anita Ducca to you dated October 31,
04: 2016. Agreed?
05: A. Yes.
06: Q. Okay. Who is Anita Ducca?
07: A. Anita Ducca is the senior
08: vice president of regulatory affairs for
09: Healthcare Distribution Alliance.
10: Q. She reports to you?
11: A. She does.
12: Q. How long have you been with
13: the HDA?
14: A. I joined in January of 2011.
15: Q. The HDA is an organization
16: that acts on behalf of its members,
17: correct?
18: A. That's correct.
19: Q. Your members include the,
20: what we refer to in the case as the big
21: three distributors, Cardinal Health,
22: AmerisourceBergen, and McKesson; is that
23: correct?
24: A. In addition to -- in

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01: addition to 29 other companies, yes.
02: Q. Okay. And you also have
03: manufacturers who are members of the
04: organization, correct?
05: A. They are in a different
06: membership category, yes.
07: Q. But they are still members?
08: A. They are members in a
09: different category.
10: Q. Okay. Mallinckrodt is a
11: member?
12: A. In the affiliate member
13: category I believe so, yes.
14: Q. Okay. Purdue?
15: A. I believe so, in the -- in
16: the affiliate member category.
17: Q. Janssen and Janssen?
18: A. Johnson & Johnson?
19: Q. Sorry. Janssen -- Janssen
20: or Johnson & Johnson?
21: A. Yes, I believe in the
22: affiliate member category.
23: Q. Actavis?
24: A. Actavis, I believe so in the

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01: affiliate member category.
02: Q. Teva?
03: A. I believe so.
04: Q. Endo?
05: A. I believe so.
06: Q. Okay. The HDA doesn't act
07: on it -- on its own, it acts in the
08: interest of its members and on behalf of
09: its members, correct?
10: MR. WEINSTEIN: Objection.
11: Objection to form.
12: Go ahead. You've just got
13: to give me a moment to object.
14: THE WITNESS: Sorry, I'm
15: sorry, I apologize.
16: We act on behalf of our core
17: members which are the distributor
18: members.
19: BY MR. PIFKO:
20: Q. Okay. You have a board,
21: correct?
22: A. We do.
23: Q. The board membership always
24: includes members from the big three,

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01: AmerisourceBergen, McKesson, and Cardinal
02: Health, correct?
03: A. In addition to the 29 other
04: members, yes.
05: Q. Okay. But the board always
06: has somebody from those companies on it?
07: A. That's correct.
08: Q. And then there's an
09: executive committee as well, correct?
10: A. That is correct.
11: Q. And what's the makeup of the
12: executive committee?
13: A. The --
14: MR. WEINSTEIN: Objection to
15: form.

16: THE WITNESS: The executive
17: committee is seven members, three
18: members from the big three,
19: AmerisourceBergen, McKesson, and
20: Cardinal have a standing position
21: on the executive committee.
22: And then there are four
23: other positions that are other
24: member companies that filter

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01: without approval from its executive
02: committee or the board, correct?
03: MR. WEINSTEIN: Objection to
04: form.
05: THE WITNESS: Again, it
06: depends on the scope of the
07: program. If there's a significant
08: cost or expenditure required, then
09: that would usually rise to the
10: level of the board. Or the
11: executive committee.
12: BY MR. PIFKO:
13: Q. The -- the HDA is not going
14: to communicate with a government agency
15: like the DEA without approval from the
16: executive committee or the board,
17: correct?
18: MR. WEINSTEIN: Objection to
19: form.
20: THE WITNESS: And again, it
21: depends on the level of
22: communication. If it's just a
23: follow-up from a call or a
24: response to a request for

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01: through kind of as -- as positions
02: become available, retirement, and
03: companies move on.
04: BY MR. PIFKO:
05: Q. The HDA doesn't take any
06: action without the approval of either the
07: executive committee or its board,
08: correct?
09: MR. WEINSTEIN: Objection to
10: form.
11: THE WITNESS: Again, it
12: depends -- it depends on what you
13: mean by action. I mean, there are
14: certain things that rise to the
15: level of the board that require
16: their approval of expenditures, et
17: cetera. But there are day-to-day
18: operations that do not require
19: approval of the board that we
20: undertake on behalf of the
21: membership.
22: BY MR. PIFKO:
23: Q. Okay. The HDA is not going
24: to undertake any project or program

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01: information, that will not
02: necessarily rise to the level of
03: the board approval and engagement.
04: BY MR. PIFKO:
05: Q. Okay. But if you're going
06: to launch some sort of detailed
07: questioning or initiative that requires
08: communication with the DEA, you're going
09: to need executive committee approval or
10: board approval, correct?
11: MR. WEINSTEIN: Objection to
12: form.
13: THE WITNESS: Again, it
14: depends on the level of -- of
15: interaction with the DEA.
16: BY MR. PIFKO:
17: Q. How about engaging with
18: members of Congress, is HDA going to
19: reach out to members of Congress without
20: approval from the board or the executive
21: committee?
22: MR. WEINSTEIN: Objection to
23: form.
24: THE WITNESS: We engage

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01: with, I mean, members of Congress
02: on a weekly basis through a
03: variety of fronts depending on
04: committee hearings or fundraisers
05: that we attend from our political
06: action committee.
07: And again, all of those
08: are -- we communicate those to the
09: board, but they are not decisions
10: that need to be made by the board
11: before HDA staff engage.
12: BY MR. PIFKO:
13: Q. Okay. So then that was
14: going to be my other question. When you
15: do communicate and interact with federal
16: agencies or state agencies or members of
17: Congress or any elected officials, you
18: always report back to either the board or
19: the executive committee, correct?
20: MR. WEINSTEIN: Objection to
21: form.
22: THE WITNESS: If it's -- if
23: it's relevant for board
24: consideration, yes.

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01: Q. The -- what follows after
02: the cover e-mail, this chronology, this
03: is accurate to the best of your
04: knowledge?
05: A. To the best of my knowledge,
06: yes. Some of it does take place before I
07: joined the organization.
08: Q. But you're familiar with
09: these events?
10: A. I am.
11: Q. Okay. And in connection
12: with providing testimony today, you've
13: made yourself familiar with all these
14: events, correct?
15: A. Yes.
16: Q. Okay. We're going to be
17: talking about several of these, starting,
18: as I talked about with Topic 4, the
19: industry compliance guidelines. You're
20: familiar with those?
21: A. I am.
22: Q. And you're familiar with the
23: history of those?
24: A. Yes.

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01: BY MR. PIFKO:
02: Q. Or the executive committee?
03: A. Or the executive committee.
04: Q. So going back to Exhibit 2.
05: You -- Ms. Ducca says that "per your
06: request, attached is a chronology of
07: interactions with the DEA."
08: Do you see that?
09: A. I do.
10: Q. You requested that she put
11: together a chronology of HDA/DEA
12: interactions in 2016?
13: A. I don't know that I
14: requested that she put it together. I
15: know that she had been basically
16: compiling the interactions.
17: Q. Okay. So she had been
18: compiling them contemporaneously with as
19: they occurred?
20: A. Right.
21: Q. And then you asked her at
22: this point for a copy of what she had
23: prepared?
24: A. Yes.

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01: Q. I want to ask you about a
02: couple items on the timeline on the first
03: page here, on HDA_MDL_00081364. Are you
04: there?
05: A. I am.
06: Q. Okay. So it says,
07: "Approximately 2005, DEA begins wholesale
08: distributor meetings."
09: Do you see that?
10: A. I do.
11: Q. Okay. And then it's got
12: three other dates on the next entry. It
13: says, "DEA sends letters on quote
14: 'responsibilities of controlled
15: substances distributors' for reporting
16: and preventing diversion to
17: distributors."
18: Do you see that?
19: A. I do.
20: Q. Those are what we refer to
21: as the Rannazzisi letters. Is that a
22: term that you're familiar with?
23: A. Yes.
24: Q. Okay. Do you know who

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01: Mr. Rannazzisi is?
02: A. I do.
03: Q. And who was he?
04: A. He at the time was the head
05: of the office of diversion control at the
06: Drug Enforcement Administration.
07: Q. And these are letters that
08: the DEA sent out, executed by
09: Mr. Rannazzisi, informing distributors
10: and members of the pharmaceutical
11: industry of their responsibilities with
12: respect to controlled substances
13: distribution, correct?
14: MR. WEINSTEIN: Objection to
15: form.
16: THE WITNESS: That's
17: correct.
18: BY MR. PIFKO:
19: Q. Okay. Then you have a,
20: "2007, DEA suspends several wholesale
21: distributor licenses."
22: Do you see that?
23: A. I do.
24: Q. Okay. I know one of those

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01: of, yes.
02: BY MR. PIFKO:
03: Q. Okay. Go to the second page
04: of the chronology, are you there?
05: A. I am.
06: Q. Okay. It says, "Spring
07: 2010, press reports of another wholesale
08: distributor registration suspension."
09: Do you see that?
10: A. I do.
11: Q. Do you know who -- whose
12: registration was suspended in the spring
13: of 2010?
14: A. I do not.
15: Q. But you know some wholesale
16: distributor's registration was
17: suspended --
18: A. According --
19: Q. -- at that time?
20: A. According to this
21: chronology, yes.
22: Q. Okay. And you believe this
23: chronology is true and correct?
24: A. To the best of my knowledge,

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01: was AmerisourceBergen, who entered into a
02: consent order on June 22nd, 2007. Are
03: you -- do you -- are you aware of that?
04: MS. ROLLINS: Objection to
05: form.
06: THE WITNESS: I'm aware in
07: general terms, yes.
08: BY MR. PIFKO:
09: Q. Okay. Are you aware of
10: other distributors who had their licenses
11: suspended in 2007.
12: MR. CRAWFORD: Objection to
13: form.
14: THE WITNESS: Not
15: specifically.
16: BY MR. PIFKO:
17: Q. So to your knowledge, that's
18: the only one?
19: MR. WEINSTEIN: Objection to
20: form.
21: BY MR. PIFKO:
22: Q. The AmerisourceBergen one?
23: MR. WEINSTEIN: Objection.
24: THE WITNESS: That I'm aware

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01: yes.
02: Q. I'm handing you what's been
03: marked as Exhibit 3.
04: (Document marked for
05: identification as Exhibit
06: HDA-Kelly-3.)
07: BY MR. PIFKO:
08: Q. It's an e-mail from Pam
09: Ritter at the HDA dated Wednesday, May
10: 30th, 2007, to a whole host members of
11: the pharmaceutical industry. It's
12: Bates-labeled HSI_MDL_00620224 through
13: 228.
14: MR. WEINSTEIN: You can
15: take -- take a moment.
16: BY MR. PIFKO:
17: Q. Take a moment to review that
18: and let me know when you're ready.
19: Do you know who Pam Ritter
20: is?
21: A. Yes.
22: Q. Who is Pam Ritter?
23: A. Pam Ritter was the
24: administrative assistant for the

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01: department -- the government affairs
02: department at HDA.
03: Q. Okay. What's the government
04: affairs department?
05: A. The government affairs
06: department is the department that I run
07: within the organization. It is the
08: department that houses our regulatory
09: affairs, federal government affairs, and
10: state government affairs teams.
11: Q. And Pam Ritter stills work
12: at the HDA?
13: A. She is no longer employed at
14: the HDA.
15: Q. Okay. When did she leave?
16: A. She retired at the end of
17: 2018.
18: Q. So have you -- you're
19: obviously are familiar with something
20: called the regulatory affairs committee?
21: A. I am, yes.
22: Q. That's a committee that's
23: within your purview?
24: A. Yes, it is.

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01: A. I see it.
02: Q. Okay. And it's asking for a
03: telephone call to be held.
04: A. Yes.
05: Q. Do you see that?
06: A. I do.
07: Q. Okay. And it says the
08: purpose of the call is -- I'm going to
09: quote here, it says, "At the May 17th --
10: which is 2007. "At the May 17th
11: executive committee, there was a
12: discussion about recent DEA activities to
13: involve wholesale distributors in efforts
14: to prevent diversion."
15: Do you see that?
16: A. I do.
17: Q. Did I read that correctly?
18: A. Yes.
19: Q. Okay. And as a result of
20: what HDA is calling recent DEA activities
21: to involve wholesale distributors in
22: efforts to prevent diversion, the
23: executive committee requested that HDA
24: become involved and come up with some

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01: Q. Okay. That -- that includes
02: some subset of members?
03: A. Yes, it does.
04: Q. Okay. But that -- at all
05: times, that includes AmerisourceBergen,
06: McKesson and Cardinal Health, correct?
07: A. If they are able to
08: participate, yes.
09: Q. Okay. But they're standing
10: members of that committee?
11: A. They -- yeah, as are the
12: rest of the members of the association,
13: yes.
14: Q. Okay. How about
15: manufacturers? Are manufacturers --
16: A. No.
17: Q. -- part of that committee?
18: A. No.
19: Q. So there's a thread of
20: e-mails here, but it goes back to one
21: dated May 25th, 2007.
22: Do you see that?
23: It's sent by Ms. Ritter, but
24: the signature on it is from Anita.

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01: strategies to interact with DEA, correct?
02: A. Yes.
03: Q. Okay. And so it says, "In
04: consultation with our outside counsel, we
05: are looking at covering the following
06: points at such a DEA meeting."
07: Do you see that?
08: A. I do.
09: Q. Okay. It's got Items 1, 2,
10: 3.
11: "One, give the DEA an
12: overview of our industry; two, discuss
13: limitations of the industry." And three,
14: which is in bold, it says, "Provide
15: specific suggestions for efforts that
16: HDMA might offer to work on with the DEA
17: as a means to show good faith and also to
18: direct them to solutions that are
19: feasible for distributors."
20: Do you see that?
21: A. I do.
22: Q. And then it says that,
23: during this call that is being requested
24: to be held in early June, it says, "We

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01: particularly wish to focus on the third
02: item during this planned conference
03: call."
04: Do you see that?
05: A. I do.
06: Q. Do you agree with that?
07: MR. WEINSTEIN: Objection to
08: form.
09: THE WITNESS: I agree that's
10: what it says.
11: BY MR. PIFKO:
12: Q. That was a focus of this
13: call that was going to be held in June?
14: A. I think so. I'll take it at
15: face value. This was when I was not in
16: the organization. But, yes.
17: Q. Okay. But you are a
18: 30(b)(6) representative for HDA, correct?
19: A. I am. I am. Yes, correct.
20: Q. Okay. And then at the
21: bottom here, it says, "I have attached a
22: draft list of possible suggestions."
23: Do you see that?
24: A. I do.

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01: Do you see that?
02: A. I do.
03: Q. And then it's got some
04: sub-bullet points. Again, it talks
05: about -- it says, "A set of guidelines
06: similar to the HDMA, guidelines for
07: distribution system integrity that would
08: be used to evaluate potential pharmacy
09: customers before entering into agreements
10: to sell controlled substances to them."
11: Do you see that?
12: A. I do.
13: Q. Did I read that correctly?
14: A. Yes.
15: Q. Okay. So, these are things
16: that the HDA was considering in response
17: to what -- what she says on the prior
18: page, "This recent DEA activities to
19: involve wholesale distributors in efforts
20: to prevent diversion," correct?
21: A. Yes.
22: Q. The third one she says is,
23: "As an extreme step, are the controlled
24: substances good candidates for a

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00056
01: Q. Okay. And then if we can --
02: if we turn the page. We see something
03: headed "Not For External Distribution,
04: Potential Areas For Joint DEA
05: Distribution Industry Focus to Help
06: Prevent Diversion."
07: Do you see that?
08: A. On which?
09: Q. It's the fourth page in.
10: A. Titled "Not For External
11: Distribution"?
12: Q. Yes. Are you there?
13: A. Yeah, yeah, yeah. I was --
14: okay. I was reading. Okay. I see it.
15: Q. Okay. And it says -- so
16: this is the attachment from Ms. Ducca
17: where she says, "I have attached a draft
18: list of possible suggestions." This is
19: that list.
20: A. Right. I see it.
21: Q. Okay. So Number 1 is,
22: "Suggest that the distribution industry
23: work together with DEA to establish
24: guide" -- "better guidelines."

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00058
01: restricted distribution program? The
02: iPledge program is an example. Although
03: no one is very enthusiastic about such
04: programs, it might be a better
05: alternative than DEA's current efforts.
06: In such a program, pharmacies and
07: prescribers would presumably have to make
08: commitments about their practices and
09: keep specific records, and distributors
10: could not sell to anyone who did not keep
11: these commitments."
12: Do you see that?
13: A. I do.
14: Q. So that's an option that was
15: being considered at this time, correct?
16: A. Yes.
17: Q. Taking stronger compliance
18: measures is not one of the topics on
19: here, correct?
20: MR. WEINSTEIN: Objection to
21: form.
22: THE WITNESS: Not on this
23: page, no.
24: BY MR. PIFKO:

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00059

01: Q. Do you know if that was
02: something that was discussed with the
03: membership at the time?
04: MR. WEINSTEIN: Objection to
05: form.
06: THE WITNESS: I do not.
07: BY MR. PIFKO:
08: Q. So to your knowledge, taking
09: stronger compliance measures was not
10: something that was in consideration in
11: response to this DEA activities, correct?
12: MR. WEINSTEIN: Objection to
13: form.
14: THE WITNESS: Again, I don't
15: know what was discussed, whether
16: that was discussed or not. It's
17: not on this document.
18: BY MR. PIFKO:
19: Q. Okay. I'm handing you
20: what's marked as Exhibit 4.
21: (Document marked for
22: identification as Exhibit
23: HDA-Kelly-4.)
24: BY MR. PIFKO:

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00061

01: bottom of her -- Anita Ducca's e-mail,
02: dated September 25, 2007.
03: Do you see that?
04: A. I do.
05: Q. Okay. She says, "Dear HDMA
06: committee members." So, the HDMA
07: committee members, that includes all
08: members?
09: MR. WEINSTEIN: Objection to
10: form.
11: THE WITNESS: In this
12: instance it appears to be the
13: regulatory affairs committee and
14: the federal government affairs
15: committee.
16: BY MR. PIFKO:
17: Q. And it's cc'd to the
18: government public policy committee as
19: well?
20: A. Government public policy
21: council.
22: Q. Oh, council. Okay.
23: Those all include
24: representatives from all the HDA

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00060

01: Q. This is another e-mail from
02: Ms. Ducca. The subject is HDMA DEA
03: strategy meeting, availability response
04: requested on alternative dates. It's
05: dated September 26, 2007. And it's got
06: another e-mail below also from Ms. Ducca
07: dated September 25, 2007.
08: MS. WICHT: Can you just
09: hold on until we have the
10: document --
11: MR. PIFKO: Yeah, no
12: problem. I was just going to -- I
13: was going to read the Bates label.
14: Bates label is
15: CAH_MDL_PRIORPROD_DEA07_00877471
16: through 473.
17: BY MR. PIFKO:
18: Q. So take a minute to review
19: it and let me know when you're ready.
20: A. Okay.
21: Q. All right. So on the first
22: page here again it's talking about
23: setting up some -- some meetings.
24: On the first page at the

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01: distributor members?
02: A. That participate in those
03: committees, yes.
04: Q. Okay. And again, that --
05: those include members from the big three
06: distributors, correct?
07: A. Yes.
08: Q. So she says here, "Given the
09: intensity and impact of the Drug
10: Enforcement Administration's recent
11: actions, and the concerns expressed by
12: HDMA's executive committee last week,
13: HDMA recommends developing a
14: comprehensive DEA strategy."
15: Do you see that?
16: A. I do.
17: Q. So at this time, the HDA on
18: behalf of its members was developing a
19: comprehensive DEA strategy as a result of
20: what they understood to be an -- intense
21: actions from the DEA; is that correct?
22: MR. WEINSTEIN: Objection to
23: form.
24: THE WITNESS: Yes, that is

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00063
01: correct.
02: BY MR. PIFKO:
03: Q. And then if you go to the
04: second page of the document, she outlines
05: some of the topics of discussions.
06: Do you see that?
07: A. I do.
08: Q. Okay. So she says, "Our
09: initial thoughts are" -- I'm on the
10: second paragraph at the top there. Are
11: you with me?
12: A. Yes, I am.
13: Q. She says, "Our initial
14: thoughts are to review the major DEA
15: issues."
16: Do you see that?
17: A. I do.
18: Q. And then she has in
19: parentheses what those issues are, right?
20: A. Yes.
21: Q. And one of them is
22: suspicious orders, correct?
23: A. Yes.
24: Q. And then she says, she wants

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00065
01: alternatives we can propose to DEA, or
02: specific objections we should raise?
03: What supporting information exists? Can
04: we develop a strategy for DEA's concerns?
05: Who should be involved?"
06: Do you see that?
07: A. Yes.
08: Q. So, again, there was a
09: discussion within the HDMA and its
10: members at this time about a strategy for
11: communicating with DEA, correct?
12: A. Yes.
13: Q. Another -- the
14: second-to-last bullet point, she has
15: here, she says, "What, if any, legal
16: options do we have to address all of the
17: above?"
18: Do you see that?
19: A. I do.
20: Q. So in addition to a DEA
21: strategy, HDMA and its members at this
22: time were also evaluating legal options
23: they might have to address these issues,
24: correct?

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00064
01: to develop a specific policy and
02: positions and supporting information for
03: those issues.
04: Do you see that?
05: A. Yes.
06: Q. As well as an overall
07: strategy for identifying solutions.
08: Do you see that?
09: A. I do.
10: Q. "We would also
11: comprehensively assess HDMA's role in
12: future DEA interactions."
13: Do you see that?
14: A. I do.
15: Q. I said that correctly?
16: A. Yes, you did.
17: Q. Okay. So then she says,
18: "Specific topics could include." And
19: there are several bullet points here.
20: Do you see that?
21: A. I do.
22: Q. So she says, "For suspicious
23: orders," she says, are -- I'm reading the
24: second bullet point. "Are there

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00066
01: MR. WEINSTEIN: Objection to
02: form.
03: THE WITNESS: According to
04: this, yes.
05: BY MR. PIFKO:
06: Q. You don't have any reason to
07: dispute the accuracy of this?
08: A. I don't.
09: (Document marked for
10: identification as Exhibit
11: HDA-Kelly-5.)
12: BY MR. PIFKO:
13: Q. I'm handing you what's
14: marked as Exhibit 5. It is a single-page
15: e-mail. It's Bates-labeled
16: HDA_MDL_000213427. Take a minute to
17: review it and let me know when you're
18: ready.
19: A. Okay.
20: Q. There's two e-mails in here,
21: only really one of substance. The
22: substantive e-mail is from John Gray
23: to -- is it Paul Julian dated Tuesday,
24: October 30th, 2007, and then John Gray

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01: forwards that to Scott Melville.
02: Do you see that?
03: A. I do.
04: Q. And the subject is HDMA
05: board meeting.
06: Do you see that?
07: A. Yes.
08: Q. Okay. Who's John Gray?
09: A. John Gray is the president
10: and CEO of HDA.
11: Q. To your knowledge, how long
12: has he been in that role?
13: A. Since 2004 I believe, maybe
14: '3.
15: Q. So at this time, he was
16: president and CEO of HDA?
17: A. HDMA at the time, yes.
18: Q. Okay. And do you know who
19: Paul Julian is?
20: A. Paul Julian was the board
21: member that was tasked to basically
22: represent McKesson on the HDA Board of
23: Directors.
24: Q. Okay. And then John Gray

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00069

01: the recent surge in DEA enforcement
02: around suspicious orders and methadone
03: was moved to the top of the HDMA priority
04: list."
05: Do you see that?
06: A. I do.
07: Q. Do you agree that the DEA
08: issue concerning what they call -- he
09: calls a recent surge in enforcement
10: around suspicious order was a top
11: priority of the HDMA at the time?
12: A. I do.
13: Q. He says, "The board wants
14: the association" -- that means the HDA,
15: correct?
16: A. Yes.
17: Q. -- "to quickly develop a
18: plan to deal with and work with the DEA
19: as necessary."
20: Do you see that?
21: A. I do.
22: Q. So there was discussions to
23: develop a plan to deal with the DEA at
24: this time, correct?

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00068

01: forwards this exchange to Scott Melville.
02: Do you see that?
03: A. I do.
04: Q. Do you know who Scott
05: Melville is?
06: A. I do.
07: Q. Who is he?
08: A. Scott Melville was the
09: former head of the government affairs
10: department at HDA.
11: Q. Is Scott Melville still
12: there?
13: A. He is not.
14: Q. So did you take over his
15: position?
16: A. I did.
17: Q. And Anita Ducca reported to
18: him at this time?
19: A. She did.
20: Q. So John Gray writes to Paul.
21: He says, among other things, if you are
22: -- are you there?
23: A. I am.
24: Q. "The DEA issue concerning

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00070

01: A. Yes.
02: Q. In response to this recent
03: surge in enforcement around suspicious
04: orders, correct?
05: A. Yes.
06: Q. Then he says, "Our first
07: step will be to assemble a legal task
08: force of member company attorneys
09: (inhouse or outside counsel) to meet with
10: our staff and discuss a course of action
11: with the DEA."
12: Do you see that?
13: A. I do.
14: Q. Then he says, "Is there
15: someone within your McKesson legal team
16: that could participate on this task
17: force?"
18: Do you see that?
19: A. I do.
20: Q. Are you aware of whether
21: such a task force was in fact formed?
22: A. Not specifically. I know
23: there were subsequent groups that were
24: formed, but I don't know if there was a

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00071

01: legal task force. In fact, I'm not aware
02: of a legal task force that was formed
03: specifically for this purpose.
04: Q. Okay. Are you aware that
05: either inhouse or outside counsel from
06: HDMA's distributor members participated
07: in discussions about this surge in DEA
08: enforcement around suspicious orders?
09: MR. WEINSTEIN: Objection to
10: form.
11: THE WITNESS: Not specific
12: meetings.
13: BY MR. PIFKO:
14: Q. But you don't have any
15: reason to disagree with this?
16: MR. WEINSTEIN: Objection to
17: form.
18: THE WITNESS: I don't.
19: BY MR. PIFKO:
20: Q. Did Anita Ducca tell you
21: that there was no such group?
22: MR. WEINSTEIN: Objection to
23: form.
24: THE WITNESS: She did not.

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00072

01: BY MR. PIFKO:
02: Q. Is Anita Ducca the person
03: who would know for sure whether such a
04: group was formed?
05: MR. WEINSTEIN: Objection to
06: form.
07: THE WITNESS: I can't say
08: for certain whether she would know
09: or not.
10: (Document marked for
11: identification as Exhibit
12: HDA-Kelly-6.)
13: BY MR. PIFKO:
14: Q. I'm handing you what's been
15: marked as Exhibit 6. Exhibit 6 is a
16: PowerPoint presentation Bates-labeled
17: HDA_MDL_000143030 through 043 or 143043.
18: According to the metadata,
19: which is attached on the first page of
20: this document, it was last modified
21: December 10th, 2007, and the file name
22: was slide for -- "Slides for Packaging
23: Call, 12/10/2007."
24: Take a minute to review this

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00073

01: and let me know when you're ready.
02: You're of course free to
03: review as much of the document as you see
04: fit, but I'm only going to ask you about
05: a couple pages of it.
06: A. Okay.
07: Q. Are you familiar with the
08: format of these slides? Is that the HDMA
09: logo on the bottom?
10: MR. WEINSTEIN: Objection to
11: form.
12: THE WITNESS: I -- I am --
13: yes, that is a common slide format
14: that we have used.
15: BY MR. PIFKO:
16: Q. And when you have these
17: conference calls, sometimes they have
18: webinars or you share the PowerPoint
19: presentations with people and you go
20: through them when you have a call?
21: A. Sometimes.
22: Q. Okay. This is the kind of
23: PowerPoint that you might share with your
24: members during a call?

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00074

01: MR. WEINSTEIN: Objection to
02: form.
03: THE WITNESS: It could be.
04: I don't know if this specific
05: PowerPoint was shared with members
06: or not. In fact, I'm not even
07: sure who the author is. I can't
08: imagine --
09: BY MR. PIFKO:
10: Q. That was going to my -- be
11: my next question. Do you know who
12: K. Baskette is?
13: A. I do not.
14: Q. This was produced by HDMA,
15: do you have any reason to dispute the
16: authenticity of this document?
17: A. I do not.
18: Q. The first slide here says,
19: "Tomorrow's Outcome?"
20: Do you see that?
21: A. Yes.
22: Q. "What are the impacts on our
23: members?"
24: Do you see that?

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00075

01: A. I do.
02: Q. "Can we identify common
03: themes and problems?"
04: Do you see that?
05: A. I do.
06: Q. And then it says, "Should
07: we," and it's got some bullet points.
08: Do you see that?
09: A. Yes.
10: Q. One of them is, "Challenge
11: the DEA."
12: Do you see that?
13: A. Yes.
14: Q. At this time in late 2007 in
15: response to this surge in enforcement
16: activity, one of the strategies HDMA and
17: its members were considering was to
18: challenge the DEA, correct?
19: MR. WEINSTEIN: Objection to
20: form.
21: THE WITNESS: Yes.
22: BY MR. PIFKO:
23: Q. It says on the next page,
24: "DEA will be here to describe their

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00077

01: Do you see that?
02: A. Yes. That's what it says,
03: yes.
04: Q. Turn to the third page of
05: the document, of the -- the slides. So
06: it's technically the fourth page of the
07: document. "Suspicious orders - policy
08: questions" is the heading of the slide.
09: Do you see that?
10: A. I do.
11: Q. Halfway down the slide it
12: says, "Should we support DEA's efforts?"
13: Do you see that?
14: A. Yes.
15: Q. So there are some questions
16: about whether HDMA and its members were
17: going to support DEA's efforts, correct?
18: A. Yes.
19: MS. MACKAY: Object to form.
20: MR. WEINSTEIN: Objection to
21: form. Just got to give a second
22: after the question.
23: THE WITNESS: Oh, I'm sorry.
24: BY MR. PIFKO:

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00076

01: expectations."
02: Do you see that?
03: A. I do.
04: Q. And it -- it gives some
05: examples of what HDA understands their
06: expectations to be at this time.
07: Do you see that?
08: A. Yes.
09: Q. "Know your customer better,"
10: correct?
11: A. That's what it says.
12: Q. "Have processes/controls in
13: place to detect suspicious orders,"
14: correct?
15: A. Yes.
16: Q. "Stop 'suspicious' order
17: sales" -- underlined -- "before
18: shipment."
19: Do you see that?
20: A. Yes.
21: Q. That's correct?
22: A. Yes.
23: Q. "Less interested in reports
24: after shipment."

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00078

01: Q. One of the bullet points is,
02: "Develop business practices," which is --
03: business practices is in quote.
04: Do you see that?
05: A. I do.
06: Q. Do you now understand what
07: that refers to?
08: A. I -- I think what it led to,
09: yes.
10: Q. The industry compliance
11: guidelines, correct?
12: A. Yes.
13: Q. And then it says,
14: "Alternatively do we want to challenge
15: DEA's expectations?"
16: Do you see that?
17: A. Yes.
18: Q. And that was something else
19: HDMA and its members were considering at
20: this time, correct?
21: MS. MACKAY: Object to form.
22: THE WITNESS: Again, I think
23: there was a variety of
24: considerations going on at the

p. 00078

00079

01: time, yes.
02: BY MR. PIFKO:
03: Q. But this was one of them,
04: correct?
05: A. According to this, yes.
06: Q. Again, it says, "What are
07: our legal options?"
08: Do you see that?
09: A. I do.
10: Q. So there were some
11: evaluations of what legal strategies can
12: be employed to challenge the DEA's
13: expectations?
14: MR. WEINSTEIN: Objection to
15: form.
16: THE WITNESS: Again, I think
17: those considerations were being
18: discussed.
19: (Document marked for
20: identification as Exhibit
21: HDA-Kelly-7.)
22: BY MR. PIFKO:
23: Q. I'm handing you what's
24: marked as Exhibit 7, it is a two-page

p. 00079

00081

01: BY MR. PIFKO:
02: Q. Okay. So you agree it's
03: roughly within that time frame?
04: MR. WEINSTEIN: Objection to
05: form.
06: THE WITNESS: I'll agree
07: that it was in that time frame.
08: BY MR. PIFKO:
09: Q. At the bottom of the first
10: page of the letter, HDMA tells DEA, "Our
11: objective is to find an effective process
12: for the DEA and our members to achieve
13: the common goals of reducing the
14: potential for diversion in a less
15: adversarial environment."
16: Do you see that?
17: A. I do.
18: Q. That's what HDMA told DEA at
19: this time, correct?
20: A. It's in the letter that we
21: sent to DEA, yes.
22: (Document marked for
23: identification as Exhibit
24: HDA-Kelly-8.)

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00080

01: document. It's a letter on HDMA
02: letterhead dated July 25, 2007, from
03: Scott Melville. It's Bates-labeled
04: CAH_MDL2804_02489197, through 198. Take
05: a minute to review that and let me know
06: when you're done.
07: A. Okay.
08: Q. So this is -- this letter
09: Exhibit 7 is HDMA requesting a meeting
10: with DEA to discuss suspicious orders,
11: correct?
12: A. Correct.
13: Q. This is -- it's dated
14: July 25, 2007. That's approximately a
15: month after AmerisourceBergen entered --
16: entered into a consent order with the
17: DEA, correct?
18: MS. ROLLINS: Objection to
19: form.
20: THE WITNESS: I'll take -- I
21: don't know the specific date when
22: that consent decree was entered
23: into. I'm thinking it's in that
24: time frame.

p. 00080

00082

01: BY MR. PIFKO:
02: Q. I'm handing you a single
03: page e-mail from Ms. Ducca marked as
04: Exhibit 8. It's Bates-labeled
05: CAH_MDL2804_012489160.
06: It's from Ms. Ducca dated
07: October 28, 2011, to Cardinal Health's
08: Robert Giacalone.
09: A. Giacalone.
10: Q. Giacalone.
11: Take a minute to review it,
12: and I just have a couple questions about
13: this.
14: A. Okay.
15: Q. So in it, Ms. Ducca is
16: explaining the history of some of the
17: negotiations and discussions regarding
18: the industry compliance guidelines,
19: correct?
20: A. Yes.
21: Q. Okay. And you could see
22: from the e-mail there are several
23: attachments, if you look on the header.
24: A. I see that.

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00083

01: Q. Okay. And then she says,
02: there's there -- there were three
03: meetings with DEA on the ICG guidelines,
04: one, April 15, 2008, one June 4, 2008,
05: one in September 2008.
06: Do you see that?
07: A. I do.
08: Q. And then she says she
09: attached a summary of the first one.
10: Do you see that?
11: "I've included a summary of
12: the first one."
13: A. Yes, yes.
14: Q. And then she says, "Labeled
15: draft since I didn't want it to look
16: final if it ever 'got out.'"
17: Do you see that?
18: A. I do.
19: Q. And then she says, "Also,
20: the second meeting consisted of DEA
21: giving us verbal feedback on their review
22: of the draft ICG that we gave them."
23: Do you see that?
24: A. I do.

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00085

01: BY MR. PIFKO:
02: Q. I'm going to hand you some
03: of the attachments, starting with her
04: summary of the September 7th, 2007,
05: meeting with DEA. Exhibit 9.
06: This is a two-page document,
07: Exhibit 9, Bates-labeled
08: CAH_MDL2804_02489199 through 200. Take a
09: minute to review this. And let me know
10: when you're done.
11: A. Okay.
12: Q. This was the meeting that
13: was held in response to the request that
14: HDA made on July 25th, 2007, correct?
15: This is a summary of that meeting,
16: correct?
17: A. I believe so, yes.
18: Q. Which is referred to in
19: Exhibit 7, right? That's the letter.
20: A. Yes.
21: Q. Okay.
22: MR. WEINSTEIN: It says
23: July 25, 2008, on the record here.
24: But it's 2007, just to be clear.

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00084

01: Q. "This is, therefore, a
02: summary of that feedback."
03: Do you see that?
04: A. I do.
05: Q. "Again, we never called it
06: 'final' since I was more interested in
07: finishing the ICG than in perfecting a
08: summary."
09: Do you see that?
10: A. I do.
11: Q. "For the third meeting I
12: didn't do a summary," she says.
13: Do you see that?
14: A. I do.
15: Q. And then she says, "Also
16: included is a summary of a meeting HDMA
17: had with DEA in September of '07 just to
18: ask them what was going on with their
19: meetings with distributors."
20: Do you see that?
21: A. I do.
22: (Document marked for
23: identification as Exhibit
24: HDA-Kelly-9.)

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00086

01: MR. PIFKO: Oh, I said that,
02: okay.
03: MR. WEINSTEIN: Yeah, yeah.
04: BY MR. PIFKO:
05: Q. So this meeting included,
06: from HDMA, Scott Melville, Anita Ducca,
07: and David Durkin, who's outside counsel
08: for HDA, correct?
09: A. Correct.
10: Q. And DEA attendees included
11: Mark Caverly, Cathy Gallagher, Mike
12: Mapes, and Lisa Sullivan, correct?
13: A. Correct.
14: Q. So it's got different
15: headings, summary, key takeaways,
16: additional points DEA made included,
17: conclusion, and then HDMA questions and
18: assessment.
19: Do you agree those are the
20: headings she has?
21: A. I agree.
22: Q. In her summary section on
23: the first page -- so one of the things
24: that HDA requested in the July 25th,

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00087

01: 2007, letter, Exhibit 7, was to
02: understand the -- what we called the
03: distributor initiative. And there is
04: some discussion here that Mike Mapes
05: provided about that.
06: Do you see that?
07: MR. WEINSTEIN: Objection to
08: form.
09: THE WITNESS: Yes.
10: BY MR. PIFKO:
11: Q. Okay. So the summary that
12: Ms. Ducca prepared says that, "Mr. Mapes
13: noted that DEA had met with approximately
14: 15 to 20 wholesale distributors one on
15: one. They had prioritized who to meet
16: with on a combination of wholesale
17: distributor sales volume and tracing back
18: to where they felt the source of products
19: for illicit internet pharmacies were
20: located."
21: Do you see that?
22: A. I do.
23: Q. Do you have any reason to
24: dispute that that's what DEA told HDMA

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01: distributor to 'know their customers.'"
02: Do you see that?
03: A. I do.
04: Q. Do you have an -- any reason
05: to dispute that these were key takeaways
06: from the meeting?
07: A. I do not.
08: Q. Then she has under her
09: heading additional points DEA made
10: included.
11: Do you see that?
12: A. Yes.
13: Q. The second one says, "DEA
14: provided examples of what a
15: distributor" -- "a wholesale distributor
16: should do to 'know their customers' and
17: what to look for."
18: Do you see that?
19: A. I do.
20: Q. Do you have any reason to
21: dispute that DEA during this meeting
22: provided examples of what distributors
23: should do to know their customers?
24: A. I do not.

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00088

01: during this meeting?
02: A. I do not.
03: Q. Then she says, key takeaways
04: from the meetings are -- from the meeting
05: were, first bullet point, "DEA's policy
06: was to expect more than just reporting
07: suspicious orders."
08: Do you see that?
09: A. I do.
10: Q. Second bullet point, "Simply
11: complying with the 'suspicious orders'
12: regulatory requirement does not mean, in
13: the agency's view, that the registrant is
14: making" -- "maintaining an effective
15: program to detect and prevention
16: diversion."
17: Do you see that?
18: A. I do.
19: Q. Did I read that correctly?
20: A. You did.
21: Q. Third bullet point, "DEA
22: indicated that they did not have the
23: resources to inspect every pharmacy;
24: therefore, it was important for the

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00090

01: Q. Going to the second page,
02: second-to-last bullet point at the top of
03: that page, "DEA also indicated that they
04: were not going to make a decision for the
05: wholesale distributor as to when an order
06: was suspicious."
07: Do you see that?
08: A. I do.
09: Q. "They feel this is up to the
10: distributor."
11: Do you see that?
12: A. I do.
13: Q. Do you have any reason to
14: dispute that this is what DEA told HDMA
15: during this meeting?
16: A. I do not.
17: Q. Last bullet point. "DEA
18: suggested that distributors should check
19: on the pharmacies' prescribing
20: physicians. They pointed to some states
21: having online systems by which a
22: distributor could check to see if a
23: prescribing physician had a valid DEA
24: registration. DEA suggested that

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00091

01: distributors ask who the doctors are that
02: are prescribing, where the pharmacy is
03: geographically with respect to its
04: prescribing doctors, and the patient
05: population."
06: Do you see that?
07: A. I do.
08: Q. Any reason to dispute that
09: that's something that DEA told HDMA
10: during this meeting?
11: A. I do not.
12: Q. And per the normal practice,
13: HDMA would have communicated this
14: information back to its members after the
15: meeting occurred, correct?
16: MR. WEINSTEIN: Objection to
17: form.
18: THE WITNESS: Correct.
19: (Document marked for
20: identification as Exhibit
21: HDA-Kelly-10.)
22: BY MR. PIFKO:
23: Q. I'm handing you what's
24: marked as Exhibit 10. For the record,

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00093

01: suspicious orders, correct?
02: A. Correct.
03: Q. And ultimately HDMA and its
04: members decided to move forward with that
05: project, correct?
06: A. Correct.
07: Q. If you look back at
08: Exhibit 9, in her summary, Ms. Ducca
09: references that, she says that "DEA
10: provided us with their latest
11: organizational chart," on the first page.
12: I don't know if you see that there. And
13: explained the responsibilities of each
14: section.
15: A. Yes.
16: Q. Okay. So going to
17: Exhibit 10, this is -- Exhibit 10 is
18: Ms. Ducca on Wednesday, January 2, 2008,
19: sending to a consultant HDMA hired on
20: behalf of its members to put together
21: this best practices, some background
22: information and a scope of work, correct?
23: MR. WEINSTEIN: Objection to
24: form.

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00092

01: it's a multiple-page document
02: Bates-labeled HDA_MDL_000151104 through
03: 151118. Take a minute to review
04: Exhibit 10 and let me know when you're
05: ready.
06: MR. WEINSTEIN: I think I
07: have the last Bates as 119, just
08: for the record.
09: MR. PIFKO: Oh, I did -- I
10: skipped that. Sorry. I didn't
11: see that was there. Yeah, so it
12: goes through 119.
13: THE WITNESS: Okay.
14: BY MR. PIFKO:
15: Q. Are you ready?
16: A. Yes.
17: Q. So as we discussed when we
18: looked at Exhibit 3, in response to what
19: HDMA told its members was a recent DEA
20: activities to involve wholesale
21: distributors in efforts to prevent
22: diversion, HDMA and its members were
23: discussing putting together some best
24: practices or guidelines concerning

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00094

01: THE WITNESS: Correct.
02: BY MR. PIFKO:
03: Q. The consultant, his name was
04: Bill Wilson, correct?
05: A. Yes.
06: Q. She says, "Dear Bill, please
07: find the information we discussed."
08: Do you see that?
09: A. I do.
10: Q. "The last attachment
11: contains" -- "contains the 'scope of
12: work' for the project proposal."
13: Do you see that?
14: A. I do.
15: Q. The second page of this
16: document includes the -- this org chart
17: which came from the meeting with DEA,
18: correct?
19: A. Yeah. I imagine so, yes.
20: Q. And then if you turn a few
21: more pages in. So Ms. Ducca is including
22: some information that she says that --
23: background that this consultant might
24: need for his work, correct?

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00095

01: A. Correct.
02: Q. One of them is a
03: September 27, 2006, letter from
04: Mr. Rannazzisi, correct?
05: A. Correct.
06: Q. There are several pages that
07: are redacted. And then the last three
08: pages are the scope of work for this
09: consultant, correct?
10: A. Yes.
11: Q. On the first page of the
12: scope of work, which is HDMA --
13: HDA_MDL_000151117, she provides different
14: headings.
15: One of -- the number -- the
16: second heading is "Objectives."
17: Do you see that?
18: A. I do.
19: Q. Okay. And she says, "The
20: purpose of this project is to support
21: HDMA's efforts to aid its members in
22: responding to the drug enforcement
23: distributor initiative by preparing a
24: 'model' set of suspicious order business

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00097

01: Q. Okay.
02: A. Stability and suitability of
03: distributor's customers.
04: Q. The second goal of this
05: document is Letter B here, "Provide
06: guidance to healthcare distributors on
07: evaluating customer orders for controlled
08: substances to indicate when orders are
09: suspicious."
10: Do you see that?
11: A. I do.
12: Q. That's correct?
13: A. That's what it says.
14: Q. And that's one of the goals
15: of the final product?
16: MR. WEINSTEIN: Objection to
17: form.
18: THE WITNESS: It is my
19: understanding.
20: BY MR. PIFKO:
21: Q. The third one, Letter C, is,
22: "Define criteria for use by HDMA members
23: that would signal when a customer is
24: placing a suspicious order and whether

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00096

01: practices."
02: Do you see that?
03: A. I do.
04: Q. Do you agree that that was
05: the scope of work for this project?
06: A. I do at the time. Yes.
07: Q. Okay. So, she says, "The
08: final product will be a document
09: containing the business practices in the
10: form of a white paper that will" --
11: Do you see that?
12: A. I do.
13: Q. And then she's got four
14: letter points here.
15: Do you see that?
16: A. I do.
17: Q. The first one I'm
18: paraphrasing is for -- to serve as a
19: guide for evaluating the suitability of
20: distributor's customers.
21: Do you see that?
22: A. I do.
23: Q. That's correct?
24: A. Yes.

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00098

01: there should be further evaluation."
02: Do you see that?
03: A. I do.
04: MS. MACKAY: Object to form.
05: BY MR. PIFKO:
06: Q. That's correct, that was one
07: of the goals of this white paper?
08: A. That's what it states here.
09: Q. Do you have any reason to
10: dispute that was one of the goals?
11: A. I do not.
12: Q. Okay. And then the fourth
13: one is, "Suggest criteria and mechanisms
14: for healthcare distributors to design of
15: a system to stop orders prior to
16: shipment, if/when an order is determined
17: to be suspicious."
18: Do you see that?
19: A. I do.
20: Q. That was another goal of
21: this model set of suspicious order
22: business practices, correct?
23: A. Again, that's what it says
24: here, and I have no reason to dispute it.

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00099

01: Q. So going to the -- the
02: second page of the scope of work.
03: HDA_MDL_001511178. Are you there?
04: A. I am.
05: Q. The heading starts on the
06: prior page, but she says, "Background
07: information and research will include the
08: following components."
09: And then she's got letters A
10: through E.
11: Do you see that?
12: A. I do.
13: Q. Okay. So these are things
14: that the consultant is supposed to do in
15: order to put together these model set of
16: suspicious order business practices,
17: correct?
18: A. Yes.
19: Q. Okay. So one of them is to
20: evaluate DEA regulations and guidance
21: provided to healthcare distributors.
22: Do you see that?
23: A. I do.
24: Q. This includes historic

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00101

01: form.
02: MS. MACKAY: Objection to
03: form.
04: THE WITNESS: It says where
05: available, yes.
06: BY MR. PIFKO:
07: Q. And then it says,
08: "Interviewing at least eight, as many as
09: ten, HDMA member companies."
10: Do you see that?
11: A. I do.
12: Q. And then it's got several
13: bullet points about what the interviews
14: are supposed to include.
15: Do you see that?
16: A. I do.
17: Q. One of them is, "Identify
18: preferences for content of such
19: guidances."
20: Do you see that?
21: A. I do.
22: Q. Another one is, "Define a
23: mechanism for stopping shipments that are
24: suspicious before they are released from

p. 00101

00100

01: information, the controlled substances
02: manual, a report to the Department of
03: Justice on suspicious orders for listed
04: chemical handlers, and more recent DEA
05: guidelines -- or guidance such as the
06: 2006 Rannazzisi letter, Kyle Wright's
07: presentation to the HDMA.
08: Do you see that?
09: A. Yes.
10: Q. Okay. That was one of the
11: things that this consultant was supposed
12: to look at to prepare these, correct?
13: A. Yes.
14: Q. Another thing was, it says,
15: "Obtaining where available copies of HDMA
16: member companies' internal suspicious
17: order business practices."
18: Do you see that?
19: A. I do.
20: Q. So one of the things that
21: this consultant was supposed to do was
22: collect the suspicious order business
23: practices from HDMA members, correct?
24: MR. WEINSTEIN: Objection to

p. 00100

00102

01: a warehouse."
02: Do you see that?
03: A. I do.
04: Q. "Identify information that
05: is either nonessential, unsuitable or
06: lacks flexibility to be applicable across
07: HDMA's highly varied membership."
08: Do you see that?
09: A. I do.
10: Q. Those were all things that
11: the consultant was supposed to discuss in
12: his interviews with the member companies?
13: A. That's what this stipulates,
14: yes.
15: Q. Then another thing he was
16: supposed to consider was, "Input from
17: HDMA's outside counsel."
18: Do you see that?
19: A. I do.
20: Q. It says, "HDMA's outside
21: counsel is currently preparing
22: information pertaining to suspicious
23: order business practices."
24: Do you see that?

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00103

01: A. Best practices, yes.
02: Q. "The information being
03: prepared is based on his experience with
04: HDMA members and DEA expectations and it
05: is anticipated will address some of the
06: conditions that should be built into a
07: set of suspicious order business
08: practices."
09: Do you see that?
10: A. Yes.
11: Q. So that's another thing this
12: consultant was supposed to be
13: considering?
14: A. According to this, yes.
15: Q. Any reason to dispute that?
16: A. No.
17: Q. Letter E is, "Review of
18: previous HDMA guidelines and other
19: HDMA-generated materials pertaining to
20: suspicious orders and related compliance
21: programs."
22: Do you see that?
23: A. I do.
24: Q. You're aware that at this

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00105

01: MR. WEINSTEIN: Objection to
02: form.
03: THE WITNESS: Correct.
04: BY MR. PIFKO:
05: Q. So then item 4, she has is,
06: project steps, cost and timing. So the
07: first step is designed to -- she wants
08: the consultant to design the interview
09: instrument.
10: Do you see that?
11: A. I do.
12: Q. And then if we turn the
13: page, the next step is contacting HDMA
14: members to request copies of their
15: current suspicious orders business
16: practices.
17: Do you see that?
18: A. I do.
19: Q. So we discussed this before.
20: This was Item B as some of the documents
21: that the consultant was supposed to use
22: to develop these, correct?
23: A. Yes.
24: Q. And then she says, "HDMA can

p. 00105

00104

01: time, HDMA had other guidelines for
02: suspicious orders, correct?
03: MR. WEINSTEIN: Objection to
04: form.
05: THE WITNESS: I don't know
06: that there were other guidelines
07: for suspicious orders.
08: BY MR. PIFKO:
09: Q. Okay. We'll get to that in
10: a minute. Then it says underneath there,
11: "To the extent possible, the final
12: document should be designed in
13: recognition of the highly varying nature
14: of the wholesale distribution in terms of
15: individual HDMA member size, customer
16: base and needs, physician" -- "physical
17: location, information technology, et
18: cetera."
19: Do you see that?
20: A. I do.
21: Q. So you understood that these
22: guidelines were supposed to be adaptable
23: so that they could be implemented by any
24: of HDA's members, correct?

p. 00104

00106

01: facilitate this by sending an e-mail to
02: our members making the request."
03: Do you see that?
04: A. I do.
05: Q. So you understand that and
06: agree that HDMA was going to request
07: copies of its members' suspicious order
08: business practices so that they could be
09: used for this project, correct?
10: MS. MACKAY: Objection to
11: form.
12: THE WITNESS: That's what I
13: understand, yes.
14: BY MR. PIFKO:
15: Q. And then it says, "Identify
16: an appropriate individual within the
17: company with whom to conduct the
18: interview as described in 3-C above."
19: Do you see that?
20: A. Yes, I do.
21: Q. And then conduct the
22: interview, right?
23: A. Yes. I see that.
24: Q. Okay. And so -- and then

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00107

01: Item 3 was to then put pen to paper and
02: draft the guidelines, correct?
03: A. Item -- yes, Item 3, yes,
04: prepare the draft.
05: Q. And then she sets a deadline
06: of January 30th so that HDMA staff
07: committees and outside counsel can review
08: them, correct?
09: A. That's what it says, yes.
10: Q. And then she says, "There
11: may be some meetings with the government
12: and public policy council which is
13: scheduled for February 12th and 13th, and
14: maybe he needs to participate in those
15: meetings."
16: Do you see that?
17: A. I do.
18: Q. And then there's going to
19: be -- they are going to be discussing the
20: draft and obtaining feedback from the
21: committee, correct?
22: A. That's what it says.
23: Q. Then to the extent
24: necessary, Items 5 and 6 talk about how

p. 00107

00109

01: CAH_MDL2804_02201910 through 1916.
02: MR. WEINSTEIN: Is there a
03: date on this document, Mark?
04: MR. PIFKO: Not on this one.
05: BY MR. PIFKO:
06: Q. Take a minute to review this
07: and let me know when you're done. Before
08: you get mired in the details -- take as
09: much time as you need -- I just want to
10: confirm.
11: So as we know from the other
12: e-mails and discussion on this best
13: practices guidelines issue, the HDA's
14: predecessor had some sort of other
15: suspicious order monitoring guidelines,
16: correct?
17: MR. WEINSTEIN: Objection to
18: form.
19: MR. PADGETT: Object to
20: form.
21: MS. WICHT: Object to the
22: form.
23: THE WITNESS: Again, I've
24: not seen this before. But I will

p. 00109

00108

01: the consultant might need to make
02: revisions to the draft, agree?
03: A. Agree.
04: MR. WEINSTEIN: Mark, is
05: this a good time for a break?
06: We've been going about an hour and
07: a quarter.
08: MR. PIFKO: Sure.
09: THE VIDEOGRAPHER: The time
10: is 10:10 a.m. We are going off
11: the record.
12: (Short break.)
13: THE VIDEOGRAPHER: The time
14: is 10:24 a.m. We are back on the
15: record.
16: (Document marked for
17: identification as Exhibit
18: HDA-Kelly-11.)
19: BY MR. PIFKO:
20: Q. I'm handing you what's
21: marked as Exhibit 11. For the record,
22: it's a document, a few pages long, with
23: the heading "NWDA Suspicious Order
24: Monitoring System." It's Bates-labeled

p. 00108

00110

01: take you at your word, yes.
02: BY MR. PIFKO:
03: Q. Well, she comments that one
04: of the things in Exhibit 10 that he's
05: supposed to review is the previous HDMA
06: guidelines.
07: Do you recall that?
08: MR. WEINSTEIN: Where are
09: you referring to, Mark?
10: MR. PIFKO: On Exhibit 10,
11: in the scope of work Section 3-E.
12: For the record, that's on
13: HDA_MDL_000151118.
14: BY MR. PIFKO:
15: Q. My question is, you agree
16: there were previous guidelines. She
17: makes reference to it in the scope of
18: work here, correct?
19: A. She did make -- I agree she
20: did make a reference to it. And this is
21: an example of those guidelines, I
22: imagine. Yes.
23: Q. To your knowledge, these are
24: dated around the '80s?

p. 00110

00111

01: MR. WEINSTEIN: Objection to
02: form.
03: THE WITNESS: I have -- I
04: have no idea when these are dated.
05: BY MR. PIFKO:
06: Q. Okay. Did you discuss
07: these, or any prior HDA or its
08: predecessor entity guidelines in
09: preparing for depositions with anybody?
10: A. I have not seen this
11: document before.
12: Q. Did you undertake any effort
13: to familiarize yourself with HDA's prior
14: suspicious order guidelines in connection
15: with preparing for this deposition?
16: A. Other than the ICGs, no,
17: nothing.
18: Q. NWDA is a predecessor name
19: for HDA correct?
20: A. That's correct.
21: Q. National Wholesale
22: Druggists' Association, correct?
23: A. Correct.
24: Q. Okay. Do you have any

p. 00111

00113

01: which will disclose to the wholesaler
02: suspicious orders of controlled
03: substances."
04: Do you see that?
05: A. I do.
06: Q. Do you have an understanding
07: that that is something that wholesale
08: distributors are required to do?
09: MR. WEINSTEIN: Objection to
10: form.
11: THE WITNESS: I do.
12: BY MR. PIFKO:
13: Q. Then it -- a little bit
14: further down in that paragraph, it says,
15: "The requirement is to monitor individual
16: orders by measuring dosage units within
17: each order and to examine for suspicious
18: volumes. Special emphasis should be
19: placed on unusual or sudden increases
20: with the volume of invoice lines
21: processed by the average wholesaler.
22: This task becomes increasingly difficult
23: as the number of products and dosage
24: sizes increase."

p. 00113

00112

01: reason to dispute that these are
02: guidelines put out on suspicious order
03: monitoring, put out by the NWDA?
04: MR. WEINSTEIN: Objection to
05: form.
06: THE WITNESS: I have no
07: reason to dispute that.
08: BY MR. PIFKO:
09: Q. I want to direct your
10: attention -- well --
11: A. Can I read them?
12: Q. Yeah. Sure I didn't know if
13: you were ready. I was only going to ask
14: you about a couple pages.
15: A. Okay.
16: Q. But take your time to look
17: at it as much as you need.
18: A. Okay.
19: Q. You ready?
20: A. I am.
21: Q. All right. First page,
22: Section 1, "Background." It says it's --
23: "It is the responsibility of the
24: wholesaler to design and operate a system

p. 00112

00114

01: Do you see that?
02: A. I do.
03: Q. Do you understand that this
04: was foundational information for the
05: NWA's -- NWDA's suspicious order
06: monitoring system?
07: MR. WEINSTEIN: Objection to
08: form and foundation, and objection
09: to scope.
10: THE WITNESS: Again, I've --
11: I've not seen this document
12: before.
13: BY MR. PIFKO:
14: Q. Are you aware that your
15: website currently states that the NWA was
16: renamed the Healthcare Distribution
17: Management Association in 2001?
18: A. I am.
19: Q. Okay. So if these are from
20: the NWDA, they would have to be prior to
21: that date for sure, correct?
22: A. Yes.
23: Q. It's got a Section 2,
24: "Definition Of Suspicious Orders." It

p. 00114

00115

01: says, "Suspicious orders include orders
02: of unusual size, orders deviating
03: substantially from a normal pattern, and
04: orders of unusual frequency."
05: Do you see that?
06: A. Yes.
07: Q. Is that consistent with what
08: your understanding of what is stated in
09: the regulations about the definition of
10: suspicious order?
11: A. That is all that is stated
12: in -- in the regulations, yes.
13: Q. I want to -- there's page
14: numbers on the bottom of this document,
15: Page 7, which is 02201916.
16: Tell me when you're there.
17: A. I'm there.
18: Q. Okay. It says, "Single
19: Suspicious Orders," Heading 9.
20: Do you see that, right
21: before summary?
22: A. I do.
23: Q. It says, "Single orders of
24: unusual size or deviation must be

p. 00115

00117

01: is in quotes -- "to mean prior to
02: shipment."
03: Do you see that?
04: A. I do.
05: Q. Did I read that correctly?
06: A. You did.
07: Q. So do you understand this to
08: be saying that an order has to be
09: identified before shipping it?
10: MR. WEINSTEIN: Objection to
11: form, foundation, scope. And
12: calls for a legal conclusion.
13: THE WITNESS: Again, I see
14: what it says here on paper. But
15: again I'm not an attorney. I'm
16: not exactly sure what the practice
17: would require.
18: BY MR. PIFKO:
19: Q. Okay. All I'm asking you is
20: what you understand this document to be
21: saying. You understand it to be saying
22: that an order needs to be identified and
23: reported prior to shipment.
24: MR. WEINSTEIN: Mark, he

p. 00117

00116

01: reported immediately."
02: Do you see that?
03: A. I do.
04: Q. Is that consistent with your
05: understanding of what's required?
06: MR. WEINSTEIN: Objection to
07: form, foundation, and scope. And
08: calls for a legal conclusion.
09: THE WITNESS: Again, I see
10: what that -- it states. Again,
11: I'm not an attorney, so I don't
12: know what the individual practice
13: would require.
14: BY MR. PIFKO:
15: Q. Okay. Then it says here,
16: "The submission of a monthly printout of
17: after-the-fact sales will not relieve a
18: registrant from the responsibility of
19: reporting these single excessive or
20: suspicious orders."
21: Did I read that correctly?
22: A. You did.
23: Q. Then it says, "DEA has
24: interpreted 'orders'" -- the word orders

p. 00116

00118

01: said he's never seen this document
02: before.
03: THE WITNESS: I -- I can
04: read what -- what the document
05: says, yes.
06: BY MR. PIFKO:
07: Q. Is that -- is that what your
08: understanding of the document is? That's
09: all I'm asking.
10: MR. WEINSTEIN: Objection to
11: form. Objection to scope.
12: He's testified he's never
13: seen this document before. The
14: document says what it says.
15: THE WITNESS: Again, the
16: document says what it says and I
17: can read what it says.
18: BY MR. PIFKO:
19: Q. Okay. But you have English
20: comprehension. You understand when you
21: read something, right?
22: A. I -- I do have English
23: comprehension.
24: Q. Okay. So all I'm asking you

p. 00118

00119

01: is what you understand this to be saying.
02: MR. WEINSTEIN: Same
03: objections.
04: THE WITNESS: I understand
05: it says, verbatim, DEA has
06: interpreted orders to mean prior
07: to shipment.
08: BY MR. PIFKO:
09: Q. Okay. And so do you
10: understand that to mean in the context of
11: this other language in the paragraph
12: here, that that means an order has to be
13: reported prior to being shipped?
14: MR. WEINSTEIN: Objection to
15: form, foundation, scope. And
16: calls for a legal conclusion.
17: THE WITNESS: Again, that's
18: what it says. That's what I would
19: understand it to mean.
20: BY MR. PIFKO:
21: Q. Okay.
22: (Document marked for
23: identification as Exhibit
24: HDA-Kelly-12.)

p. 00119

00121

01: received so far. This is from our member
02: Henry Schein, Inc."
03: Do you see that?
04: A. I do.
05: Q. So as we discussed, one of
06: the things that the consultant was
07: supposed to do was to obtain copies of
08: the member companies' suspicious order
09: policies and procedures and incorporate
10: information from those into these model
11: guidelines, correct?
12: MR. WEINSTEIN: Objection to
13: form.
14: MS. MACKAY: Objection to
15: form.
16: THE WITNESS: Correct, yes.
17: BY MR. PIFKO:
18: Q. Okay. So this confirms that
19: HDA was, in fact, collecting these
20: procedures and sending them to their
21: consultant, correct?
22: A. Yes, according to this, yes.
23: Q. Do you have any reason to
24: dispute that that happened?

p. 00121

00120

01: BY MR. PIFKO:
02: Q. I'm handing you what's
03: marked as Exhibit 12. It's a single page
04: e-mail. Bates labeled HDA_MDL_000150198.
05: Take a minute to review that and let me
06: know when you're done.
07: A. Okay.
08: Q. So this is from Anita Ducca
09: to Bill Wilson, who is the consultant who
10: is putting together the best practices or
11: industry compliance guidelines, correct?
12: A. Yes.
13: Q. Okay. And this is dated
14: January 10, 2008.
15: Do you see that?
16: A. Yes.
17: Q. She says, "Bill, all week we
18: have been contacting our members to
19: request their suspicious order
20: information."
21: Did I read that correctly?
22: A. You did.
23: Q. "This is the first of a few
24: e-mails I'll be sending with what we

p. 00120

00122

01: A. I do not.
02: (Document marked for
03: identification as Exhibit
04: HDA-Kelly-13.)
05: BY MR. PIFKO:
06: Q. I'm handing you what's
07: marked as Exhibit 13. It's another
08: single page -- well, there's a tiny bit
09: of language on the second page.
10: MR. WEINSTEIN: And, Mark, I
11: should just say, to avoid any
12: confusion on the record, there's
13: obviously references throughout to
14: members. Mr. Kelly is obviously
15: interpreting that when you use
16: that phrase to mean the
17: distributor members.
18: If at any point you are
19: specifically referring to
20: manufacturer members, if you could
21: just make that clear, so that we
22: have a clear record, I would
23: appreciate that.
24: BY MR. PIFKO:

p. 00122

00123

01: Q. Exhibit 13 is a document
02: Bates-labeled HDA_MDL_000139414 through
03: 415.
04: MR. PIFKO: And, Brian, to
05: be clear, I understand that you're
06: trying to make your record, but
07: you can't be coaching the witness.
08: You can't be saying things like
09: he's never seen this before --
10: MR. WEINSTEIN: I absolutely
11: can --
12: MR. PIFKO: You can't be
13: saying things like --
14: MR. WEINSTEIN: -- when you
15: ask an inappropriate question.
16: MR. PIFKO: -- here -- here
17: is what the -- he's referring to.
18: You're not being deposed here.
19: Okay?
20: MR. WEINSTEIN: Mark, if you
21: ask an inappropriate question I'm
22: going to protect the record.
23: MR. PIFKO: You can -- you
24: can -- no --

p. 00123

00125

01: January 17, 2008.
02: Do you see that?
03: A. I do.
04: Q. The subject is "Rewrite."
05: And here he's sending a draft of the
06: questionnaire. You recall that that was
07: the first step of his engagement,
08: correct?
09: A. Yes.
10: Q. Okay. Do you have any
11: dispute -- any reason to dispute that
12: this is the first draft or one of the
13: drafts of his questionnaire that he was
14: going to be asking members when he
15: interviewed them?
16: MR. WEINSTEIN: Objection to
17: form.
18: THE WITNESS: I have no
19: reason to dispute that this is the
20: first draft.
21: BY MR. PIFKO:
22: Q. Okay. And one of the topics
23: that he wants to ask HDMA's members is,
24: he says, "DEA says 'know your customer.'"

p. 00125

00124

01: MR. WEINSTEIN: So ask your
02: question --
03: MR. PIFKO: -- you can
04: object to form. You can object
05: for specificity --
06: MR. WEINSTEIN: I can object
07: when you ask an inappropriate
08: question.
09: MR. PIFKO: But you can't --
10: those are speaking objections --
11: MR. WEINSTEIN: Absolutely
12: not.
13: MR. PIFKO: -- and we're not
14: going to have those. Okay?
15: MR. WEINSTEIN: Absolutely
16: not. I'm very disciplined, and
17: I'll continue to act
18: appropriately.
19: BY MR. PIFKO:
20: Q. Let me know when you're done
21: reviewing this document.
22: A. Okay.
23: Q. So this is from Bill Wilson,
24: the consultant, e-mailing Ms. Ducca on

p. 00124

00126

01: What is your understanding of that
02: statement and what as a company are you
03: doing to meet that requirement?"
04: Do you see that?
05: A. I do.
06: Q. Okay. Then there's a bunch
07: of questions. He has, "What steps do you
08: take about adding a new customer?"
09: Various questions about things people
10: could ask a new customer.
11: Do you see that?
12: A. I do.
13: Q. "How do you handle
14: discrepancies if they don't answer the
15: questions or if they leave something
16: blank?"
17: Do you see that?
18: A. No.
19: Q. Just below the block of
20: questions about adding a new customer.
21: "Based on information you gather from the
22: potential customer, how do you handle
23: discrepancies in the information" --
24: A. Okay. Okay. You -- all

p. 00126

00127
01: right. Yes.
02: Q. That was something else that
03: he was asking?
04: MR. WEINSTEIN: Objection to
05: form.
06: BY MR. PIFKO:
07: Q. To the members, correct?
08: MR. WEINSTEIN: Same
09: objection.
10: THE WITNESS: Yes. Again,
11: this is the draft. So I don't
12: know what the actual final vehicle
13: entailed or not.
14: BY MR. PIFKO:
15: Q. Okay. One of the questions
16: is, "Do you feel what you are doing now
17: should be sufficient?"
18: Do you see that?
19: A. I do.
20: Q. You understand that that was
21: something that he was asking the members?
22: MR. WEINSTEIN: Objection to
23: form.
24: THE WITNESS: Again, whether

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00129
01: A. Correct.
02: MR. WEINSTEIN: Objection to
03: form.
04: BY MR. PIFKO:
05: Q. This concerns developing
06: them, correct?
07: A. It does. I've not seen this
08: e-mail before.
09: Q. If you turn to the second
10: page. Two other questions here, "In
11: building a model for compliance, what
12: steps do you feel are essential to a good
13: compliance program?"
14: Do you see that?
15: A. I do.
16: Q. You understand that that was
17: something that was asked of HDA members
18: in connection with this project?
19: MR. WEINSTEIN: Objection to
20: form. Foundation.
21: THE WITNESS: Again, it was
22: part of the initial draft.
23: BY MR. PIFKO:
24: Q. How about, "In building a

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00128
01: that was in the final. This is a
02: draft. And again, I don't know if
03: that was the final. I know that
04: was here on the paper, but first
05: draft.
06: BY MR. PIFKO:
07: Q. Okay. You understand Topic
08: 4 is the guidelines and the process of --
09: A. Correct.
10: Q. -- gathering them, and that
11: is something that you're designated to
12: testify on about, right?
13: A. I do.
14: Q. And you have a duty to be
15: familiar with all the attributes of it,
16: correct?
17: MR. WEINSTEIN: Objection to
18: form.
19: THE WITNESS: Of the
20: document -- yes. Of the ICGs,
21: yes, and the process.
22: BY MR. PIFKO:
23: Q. Okay. And the development
24: of them, correct?

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00130
01: model for compliance, what steps do you
02: feel you could not do based on your
03: customer base?"
04: Do you see that?
05: A. I do.
06: Q. You understand that that was
07: also something that was being discussed
08: with the members in connection with
09: drafting these guidelines?
10: MR. WEINSTEIN: Objection to
11: form. Foundation.
12: THE WITNESS: Again, I think
13: it was part of the first draft,
14: yes.
15: BY MR. PIFKO:
16: Q. You recall in some of the
17: other discussions that we looked at in
18: the prior exhibits, feasibility of the
19: guidelines and adaptability was a feature
20: that HDMA and its members wanted to
21: include in the guidelines, correct?
22: MR. WEINSTEIN: Objection to
23: form.
24: THE WITNESS: Correct.

p. 00130

00131

01: BY MR. PIFKO:
02: Q. You didn't want to have
03: guidelines that its member companies
04: could not adopt, correct?
05: MR. WEINSTEIN: Objection to
06: form. Foundation.
07: THE WITNESS: Correct.
08: (Document marked for
09: identification as Exhibit
10: HDA-Kelly-14.)
11: BY MR. PIFKO:
12: Q. I'm handing you what's
13: marked Exhibit 14. For the record,
14: Exhibit 14 is a two-page document
15: Bates-labeled HDA_MDL_00213181 through
16: 82. Take a minute to review it. Let me
17: know when you're done. It's another
18: e-mail from Ms. Ducca, two e-mails from
19: her, one dated Wednesday, February 6,
20: 2008, and another one dated the same day,
21: just from an earlier time.
22: A. Okay.
23: Q. What do you know about Bill
24: Wilson's background?

p. 00131

00133

01: Do you see that?
02: A. I do.
03: Q. So there was going to be a
04: meeting on February 7th to discuss the
05: revised draft best practices, correct?
06: A. Yes.
07: Q. On the -- on the first page
08: of the e-mail she discusses a meeting
09: that occurred on January 31, 2008. If
10: you look at the attachments on the -- on
11: the header, it says, "Final slides for
12: 1/31/08."
13: Do you see that?
14: HDMA. And then it also
15: says, "HDMA 01/31/08, D. Durkin."
16: Do you see that?
17: A. I do, yes.
18: Q. Okay. You recall that one
19: of the things in the discussions with the
20: consultant was that there was a deadline
21: of January 30th to get a draft of the
22: guidelines?
23: A. I -- I do recall that, yes.
24: Q. Okay. And you agree that

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00132

01: A. I have never met Bill
02: Wilson. He was engaged during a time
03: before I got to the organization. I
04: understand that he was a consultant with
05: expertise in compliance-related issues.
06: I don't know if he had any specific DEA
07: experience or not.
08: Q. Looking at Exhibit 14, if
09: you -- you know how you read e-mails on
10: these. You have to read the back pages,
11: or the earlier pages.
12: So looking at the second
13: page, it's -- this e-mail Ms. Ducca
14: sends, Wednesday, February 6, 2008, and
15: the subject is HDMA RAC conference call
16: reminder.
17: RAC is regulatory affairs
18: committee, correct?
19: A. That's correct.
20: Q. And then it says here, "To
21: regulatory affairs committee.
22: Participants in the January 31 HDMA
23: meeting on suspicious order best
24: practices."

p. 00132

00134

01: there was a meeting on January 31, 2008,
02: to discuss the guidelines and various
03: other aspects of it, of the project?
04: A. Yes.
05: Q. So looking at this first
06: page of the first e-mail, the top, the
07: more recent one, the second paragraph,
08: she says, "The meeting went very well and
09: we had excellent member input."
10: That's discussing the
11: January 31, 2008, meeting, correct?
12: A. Yes.
13: Q. "We discussed DEA's
14: requirements, expectations and recent
15: letters, and discussed the importance and
16: use of a set of best practices and what
17: the next steps will be after they are
18: completed."
19: Do you see that?
20: A. I do.
21: Q. Then she says, "I have
22: attached the overhead slides that HDMA
23: and our outside counsel provided at the
24: meeting. They go through what we said

p. 00134

00135
01: about the above."
02: Do you see that?
03: A. I do.
04: Q. And then she says, "We also
05: reviewed a draft of best practices that
06: HDMA (a consultant and me) have put
07: together."
08: Do you see that?
09: A. I do.
10: Q. So Ms. Ducca and the
11: consultant worked together to put the
12: guidelines together?
13: A. Yes.
14: Q. And then they were discussed
15: with the member -- members at this
16: meeting, she says, based on input from
17: members at the meeting.
18: Do you see that?
19: A. I do.
20: Q. And then she says, "We
21: prepared a revised draft for additional
22: comment, and that revised draft is
23: attached."
24: Do you see that?

p. 00135

00137
01: Q. Okay. The second -- the
02: first page of the Exhibit 15 is just a
03: cover page. The second page is the
04: agenda for the discussion.
05: Do you see that?
06: A. Yes.
07: Q. So review the antitrust and
08: antiharassment policies.
09: Then, background, DEA
10: suspicious order requirements. And
11: HDMA's best practices, the efforts to
12: date. Then legal and policy perspective.
13: Then there was going to be a
14: discussion about the potential best
15: practices, questions for attendees. And
16: then a discussion, allows for member
17: input. And then discussion of model
18: modifications, areas for further review.
19: And then a discussion of next steps,
20: additional DEA issues.
21: Do you see that?
22: A. I do.
23: Q. Do you agree that this was
24: the agenda of this portion of the -- the

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00136
01: A. I do.
02: Q. Okay. And then, as we
03: discussed a moment ago, then there was
04: going to be another call on February 7th
05: to discuss the revised draft. Agree?
06: A. Yes.
07: Q. I'm going to hand you these
08: handouts from the January 31st meeting
09: starting with the first one which is
10: marked as Exhibit 15.
11: (Document marked for
12: identification as Exhibit
13: HDA-Kelly-15.)
14: BY MR. PIFKO:
15: Q. For the record, it's
16: Bates-labeled HDA_MDL_000213212 through
17: 213228.
18: Let me know when you're
19: done. Again, take as much time as you
20: need to review the document, but I'm only
21: going to ask you about a couple slides.
22: A. Okay.
23: Q. Are you ready?
24: A. I am.

p. 00136

00138
01: meeting?
02: A. I do.
03: Q. I want to go to the fourth
04: page of the exhibit. It's got a little
05: bit of a timeline here. Let me know when
06: you're there.
07: A. I'm there.
08: Q. Okay. So it says, "Best
09: practices identified as a possible
10: solution."
11: This is the solution to the
12: increased DEA enforcement activity as we
13: discussed at the beginning of the
14: deposition, correct?
15: MR. WEINSTEIN: Objection to
16: form.
17: THE WITNESS: Yes.
18: BY MR. PIFKO:
19: Q. Okay. And so the best
20: practices was identified as a solution on
21: October 16, 2007, during an HDMA-DEA
22: meeting.
23: MR. WEINSTEIN: Objection to
24: form.

p. 00138

00139
01: BY MR. PIFKO:
02: Q. Agree?
03: A. That's -- yeah, that's what
04: it says. Yes.
05: Q. Okay. And it's an HDMA
06: meeting regarding the DEA, right?
07: A. I believe it might have
08: been -- again, I'm not -- it was a --
09: either a meeting directly with DEA or
10: a -- if we -- is that on the timeline?
11: Q. That other meeting we talked
12: about with -- with --
13: A. Yeah, this was with DEA.
14: Q. Okay.
15: A. DEA participated in that
16: event.
17: Q. Okay. And then there was a
18: recommendation from outside counsel to
19: move forward on December 19, 2007, agree?
20: A. Yes.
21: Q. And then there was the
22: request for members' existing best
23: practices on January 3, 2008. Agree?
24: MR. WEINSTEIN: Objection to

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00141
01: Q. The pain coalition, that's
02: the Pain Care Forum officially?
03: A. I believe it's one and the
04: same.
05: Q. Okay. And that includes
06: manufacturers in the pharmaceutical
07: industry, correct?
08: MS. MACKAY: Objection.
09: Foundation.
10: THE WITNESS: It includes --
11: my understanding, it includes a
12: variety of constituent groups in
13: the supply chain, including
14: patient groups, and manufacturers,
15: and distributors and pharmacies,
16: et cetera.
17: BY MR. PIFKO:
18: Q. Okay. But -- so all I'm
19: asking you is the Pain Care Forum
20: includes, among others, manufacturers in
21: the pharmaceutical industry, correct?
22: MS. MACKAY: Objection.
23: Foundation.
24: THE WITNESS: That's

p. 00141

00140
01: form.
02: THE WITNESS: Yes.
03: BY MR. PIFKO:
04: Q. And then the interviews and
05: follow-up requests occurred from
06: January 7th to January 11th. Agree?
07: A. Yes.
08: Q. And then there was a
09: presentation to the pain coalition on
10: January 1st, 2010 -- or, sorry,
11: January 10, 2008.
12: Do you see that?
13: A. I do.
14: Q. Do you have an understanding
15: as to why the -- there was a presentation
16: to the pain coalition about the best
17: practices for suspicious orders?
18: A. My understanding is that was
19: a monthly meeting, that group met fairly
20: regularly. And we went to apprise them
21: of the fact that we were developing the
22: guidelines for suspicious order
23: monitoring and reporting based on recent
24: DEA actions.

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00142
01: correct.
02: BY MR. PIFKO:
03: Q. And the pain coalition, or
04: pain care foundation is specifically
05: focused on pain by its -- by definition,
06: correct?
07: MS. MACKAY: Objection --
08: MS. ROLLINS: Objection to
09: form.
10: MS. MACKAY: Objection.
11: Form. Foundation.
12: THE WITNESS: Again, the
13: Pain Care Forum -- Pain Care Forum
14: I think is the official name.
15: Again, issues and policies
16: related to the treatment of
17: individuals with pain, chronic
18: pain, terminal pain. Those types
19: of things.
20: BY MR. PIFKO:
21: Q. Treatment of pain?
22: MS. MACKAY: Objection.
23: Foundation. Form.
24: THE WITNESS: Treatment --

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00143
01: treatment of pain, yes.
02: BY MR. PIFKO:
03: Q. Pain advocacy?
04: MS. MACKAY: Same
05: objections.
06: MR. WEINSTEIN: Objection to
07: form.
08: THE WITNESS: Not so much
09: advocacy, more of just information
10: about policies that are being
11: discussed.
12: BY MR. PIFKO:
13: Q. And in connection with your
14: work for the HDA, have you attended a
15: Pain Care Forum meeting?
16: A. I personally have not.
17: Q. Have you discussed Pain Care
18: Forum meetings with your colleagues?
19: A. I am aware of past Pain Care
20: Forum meetings, yes.
21: Q. You are familiar with the
22: Pain Care Forum and its objectives and
23: its membership based on your role for the
24: HDA?

p. 00143

00145
01: Q. Do you remember discussing
02: HDA ceasing to be a member of the Pain
03: Care Forum?
04: A. Vaguely.
05: Q. Who did you discuss that
06: with?
07: A. Again, one of the
08: discussions we have on an annual basis
09: about where we are -- have resources and
10: events and groups we're participating
11: with.
12: Q. Okay. In one of these
13: annual meetings you discussed the HDA's
14: involvement with the Pain Care Forum?
15: MS. MACKAY: Form.
16: MR. WEINSTEIN: Objection to
17: form.
18: THE WITNESS: Again, there
19: was a decision made -- I don't
20: know when -- to not participate
21: with the Pain Care Forum any
22: longer.
23: BY MR. PIFKO:
24: Q. Okay. Do you know what the

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00144
01: A. Again, generally, yes.
02: Not -- I couldn't name specific members
03: other than -- the top of my head.
04: Q. The HDMA is a member of the
05: Pain Care Forum, correct?
06: A. We are no longer a member of
07: the Pain Care Forum.
08: Q. But you were?
09: A. At one point we were.
10: Q. When did you stop being a
11: member of the Pain Care Forum?
12: A. I don't know the specific
13: date.
14: Q. In the last year?
15: A. Beyond that.
16: Q. Two years ago?
17: A. Again, I don't know the
18: specific date.
19: Q. Let's do this. When did you
20: join HDA?
21: A. 2011.
22: Q. Was HDA a member of the Pain
23: Care Forum when you first joined HDA?
24: A. I don't know for certain.

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00146
01: basis for that decision was?
02: A. Just general -- didn't have
03: staffing and resources to continue to
04: send people out to meetings and events.
05: Q. Okay. We'll come back to
06: that. Next slide, Page 5 of Exhibit 15.
07: Are you there?
08: A. Yes.
09: Q. It says the desired outcome
10: of the best practices, "Agree upon
11: fundamentals of distribution industry
12: best practices for suspicious orders for
13: government public policy committee
14: review. Eventually provide to DEA."
15: Do you see that?
16: A. I do.
17: Q. Did I read that correctly?
18: A. You did.
19: Q. Is that consistent with what
20: your understanding of the desired outcome
21: was?
22: MR. WEINSTEIN: Objection to
23: form.
24: THE WITNESS: Yes, at this

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00147
01: point in time, yes.
02: BY MR. PIFKO:
03: Q. Another goal of the meeting
04: and this ongoing discussion was to reach
05: agreement among HDA's members on these
06: best practices or guidelines, correct?
07: MR. WEINSTEIN: Objection to
08: form.
09: THE WITNESS: Yes.
10: BY MR. PIFKO:
11: Q. If you go to Page 7 of
12: Exhibit 15. It's got some bullet points
13: of attributes of the system. One of them
14: is, "Develop thresholds."
15: Do you see that?
16: A. Yes.
17: Q. It says, "Calculate average
18: orders for families."
19: Do you see that?
20: A. Yes.
21: Q. "ID orders of unusual size,
22: frequency, pattern"?
23: A. Yes.
24: Q. "And stop shipments"?

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00149
01: suspicious order as far as whether it
02: could be shipped?
03: MR. WEINSTEIN: Objection to
04: form.
05: THE WITNESS: Again, yes.
06: BY MR. PIFKO:
07: Q. I want to go to Page 12 of
08: the document.
09: So then, this discusses some
10: of the next steps. Ultimately there was
11: going to be a government public policy
12: committee review of the best practices or
13: guidelines on February 12th. Agree?
14: MR. WEINSTEIN: Objection to
15: form.
16: THE WITNESS: Yes.
17: BY MR. PIFKO:
18: Q. Sorry, it's the government
19: public policy council, correct?
20: A. Correct.
21: Q. Okay. Then the executive
22: committee is going to review them on
23: February 22nd, correct?
24: A. Yes.

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00148
01: A. Yes.
02: Q. Those were all features of
03: the guidelines or best practices that you
04: were working on --
05: MR. WEINSTEIN: Objection.
06: BY MR. PIFKO:
07: Q. -- at this time?
08: MR. WEINSTEIN: Objection to
09: form.
10: THE WITNESS: Yes. It's my
11: understanding.
12: BY MR. PIFKO:
13: Q. If you go to Page 8 of the
14: document. It talks -- there's another
15: attribute. It says "shipping" --
16: "shipment decisions."
17: Do you see that?
18: A. I do.
19: Q. Four decision options.
20: Do you see that?
21: A. I do.
22: Q. So you understood there was
23: going to be various options set out for
24: what someone could do when evaluating a

p. 00148

00150
01: Q. And then you're going to
02: request a meeting with the acting DEA
03: administrator, correct?
04: A. Correct.
05: Q. And one question had was,
06: "Should the best practices become a
07: regulation?" Correct?
08: A. Correct.
09: Q. That was something that HDA
10: and its members were discussing?
11: A. Correct.
12: MS. MACKAY: Objection to
13: form.
14: BY MR. PIFKO:
15: Q. I'll direct you to Page 17
16: of Exhibit 15. Another thing that was
17: still being considered at this time was
18: whether HDA and its members would mount
19: to legal challenge to DEA, correct?
20: A. Yes.
21: Q. And then it says, "May
22: require extensive justification."
23: Do you see that?
24: A. Yes.

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Page 42

00151
01: Q. "For example, DEA changed a
02: 30-year reporting requirement to stopping
03: transactions."
04: Do you see that?
05: A. Yes.
06: Q. So one of the things that
07: HDA and its members were discussing at
08: this time in response to the DEA's
09: enforcement activity was to mount a legal
10: challenge concerning the reporting
11: requirement and whether it required
12: members to stop transactions?
13: MR. WEINSTEIN: Objection to
14: form.
15: THE WITNESS: Yes.
16: (Document marked for
17: identification as Exhibit
18: HDA-Kelly-16.)
19: BY MR. PIFKO:
20: Q. I'm handing you what's
21: marked as Exhibit 16. For the record,
22: this is another presentation from that
23: meeting. Bates-labeled HDA_MDL_000213229
24: through 213240.

p. 00151

00153
01: THE WITNESS: The ones
02: that -- that participated, yes.
03: BY MR. PIFKO:
04: Q. And so those members would
05: have been part of the discussion on
06: January 31, 2008, where these were
07: presented, correct?
08: MR. WEINSTEIN: Objection to
09: form.
10: THE WITNESS: The ones that
11: participated definitely, yes.
12: BY MR. PIFKO:
13: Q. And that included the big
14: three who participated, correct?
15: MS. ROLLINS: Objection to
16: form.
17: THE WITNESS: Again, I don't
18: have the exact list of
19: participants in front of me, but I
20: would imagine, yes.
21: BY MR. PIFKO:
22: Q. Because they're -- they're
23: on the regulatory affairs committee,
24: correct?

p. 00153

00152
01: One of the things referenced
02: in Ms. Ducca's e-mail, Exhibit 14, was
03: that she's attaching slides from HDMA and
04: the outside counsel.
05: This is the presentation
06: from HDMA's outside counsel at that
07: meeting. Please review it and let me
08: know when you're ready to discuss.
09: A. Okay.
10: Q. The discussion regarding the
11: industry compliance guidelines or best
12: practices was being facilitated through
13: the regulatory affairs committee; is that
14: correct?
15: MR. WEINSTEIN: Objection to
16: form.
17: THE WITNESS: Correct.
18: BY MR. PIFKO:
19: Q. Yes?
20: A. Yes.
21: Q. And again that included all
22: of HDA's distributor members, correct?
23: MR. WEINSTEIN: Objection to
24: form.

p. 00152

00154
01: A. Yes.
02: Q. Trying to -- so again, as we
03: talked about when I handed you this
04: exhibit, this is from HDA's outside
05: counsel. It is a presentation entitled,
06: "Suspicious Orders and Diversion
07: Prevention," which was presented at the
08: meeting on January 31st in -- at HDA's
09: offices in Arlington, Virginia, correct?
10: A. That's my understanding,
11: yes.
12: Q. If you go to the third page
13: of the document, they are laying out the
14: statutory framework and conditions of
15: registration for -- do you see that here?
16: A. I do.
17: Q. Okay. The second bullet
18: point says, "The first factor in
19: determining the public interest is the
20: maintenance of effective controls against
21: diversion into other than legitimate
22: channels," correct?
23: MR. WEINSTEIN: Objection to
24: form. Foundation.

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00155
01: THE WITNESS: Yes. That's
02: what it says.
03: BY MR. PIFKO:
04: Q. If you go to the one with
05: the Bates number 213234 it says "Prior
06: Experience" on the top.
07: A. I see it.
08: Q. It says, under the heading
09: "Prior Experience," "DEA would not tell a
10: distributor if an order is legitimate or
11: not."
12: Do you see that?
13: A. Yes.
14: Q. And then it says, "DEA would
15: tell the distributor that it must decide
16: which orders are suspicious and make a
17: sales decision."
18: Do you see that?
19: A. Yes.
20: Q. The next slide has got some
21: criteria for suspicious orders.
22: Do you see that?
23: A. I do.
24: Q. Seven bullet points,

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00157
01: A. Yes.
02: Q. Location of customer?
03: A. Yes.
04: Q. Different combinations of
05: drugs, correct?
06: MS. ROLLINS: Objection.
07: MS. MACKAY: Object to form.
08: MR. WEINSTEIN: Objection to
09: form.
10: THE WITNESS: It says only
11: phentermine, hydrocodone, and/or
12: alprazolam.
13: BY MR. PIFKO:
14: Q. Like if an order is only
15: those things, that potentially could be
16: suspicious. That's what it's saying
17: here?
18: MR. WEINSTEIN: Objection to
19: form. Foundation.
20: THE WITNESS: I imagine,
21: yes.
22: BY MR. PIFKO:
23: Q. No established business
24: credit, yes?

p. 00157

00156
01: correct?
02: A. Yes, correct.
03: Q. And these aren't simply
04: repeating unusual size, pattern or
05: frequency, correct?
06: MR. WEINSTEIN: Objection to
07: form.
08: THE WITNESS: It goes beyond
09: that.
10: BY MR. PIFKO:
11: Q. Right. It elaborates on
12: what that could mean, correct?
13: MR. WEINSTEIN: Objection to
14: form.
15: THE WITNESS: That's what it
16: says, yes.
17: BY MR. PIFKO:
18: Q. Quantities of drugs
19: purchased, correct?
20: A. Correct.
21: Q. Percentage of controlled
22: versus noncontrolled, correct?
23: A. That's what it says, yes.
24: Q. Size of orders, correct?

p. 00156

00158
01: A. Yes. That's what it says.
02: Q. Frequent large orders,
03: correct?
04: A. Yes.
05: Q. Next slide is headed
06: "Issues."
07: Second bullet point, it
08: says, "Is the failure to report an
09: unusual order a violation if the drug is
10: dispensed for a lawful purpose?"
11: Do you see that?
12: A. Yes.
13: Q. So one of the things that
14: was discussed at this meeting was whether
15: it could still be a violation of the
16: regulations in the CSA if you didn't
17: report an unusual order even if it was
18: for a lawful purpose, correct?
19: A. Again, I think this one was
20: posited as a question.
21: Q. But my point is, that was
22: something that was being discussed.
23: Whether -- whether that would be a
24: violation or not, that was something

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00159
01: people were discussing at this meeting?
02: MR. WEINSTEIN: Objection to
03: form.
04: THE WITNESS: That's -- yes.
05: BY MR. PIFKO:
06: Q. Another thing discussed, if
07: you go to the slide, 000213238. Let me
08: know when you're there.
09: A. "What has changed?"
10: Q. Yes.
11: A. Yes.
12: Q. Second bullet point, it
13: says, "The suspicious nature of the order
14: depends not on pattern of ordering
15: customer, but on patterns of registrant's
16: customer base and patterns throughout the
17: regulated industry."
18: Do you see that?
19: A. I do.
20: Q. That was something else
21: discussed at this meeting?
22: A. It -- it was.
23: Q. Also that rigid formulas
24: were -- may be insufficient as well,

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00161
01: A. Yes.
02: Q. So he attaches this draft.
03: It says, "Discussion draft for meeting,"
04: as the file name. Do you see that on the
05: first page?
06: A. Yes.
07: Q. And then the following pages
08: are that discussion draft.
09: It says, "Discussion draft,
10: 1/31/08."
11: Do you see that?
12: A. Yes.
13: Q. So this is the draft that
14: was discussed during that meeting,
15: correct?
16: A. Yes.
17: Q. So it's got several
18: features. Heading 1 is "Know Your
19: Customer."
20: Do you see that?
21: A. Yes.
22: Q. It says, "Before opening up
23: a new customer account, it is recommended
24: that the distributor obtain background

p. 00161

00160
01: correct?
02: A. That was discussed.
03: (Document marked for
04: identification as Exhibit
05: HDA-Kelly-17.)
06: BY MR. PIFKO:
07: Q. Handing you what's marked as
08: Exhibit 17. For the record, it's an
09: e-mail with an attachment. Bates-labeled
10: HDA_MDL_000141125 through 141133. This
11: is an e-mail from Mr. Wilson dated
12: Tuesday, February 5, 2008, to Ms. Ducca,
13: attaching a discussion draft of the
14: interim -- industry compliance or best
15: practices guidelines.
16: Take a moment to review this
17: and let me know when you're ready.
18: A. Okay.
19: Q. Do you recall one of the
20: attributes of the scope of work that
21: Mr. Wilson was supposed to provide was to
22: draft -- put together an initial draft
23: and then potentially attend meetings and
24: do revisions, correct?

p. 00160

00162
01: information on the customer and their
02: business, review the information for
03: discrepancies, and where appropriate,
04: verify the information."
05: Do you see that?
06: A. I do.
07: Q. And then it says, "The
08: following information is recommended,"
09: and it's got a whole host of information.
10: Do you see that?
11: A. Yeah. The following is
12: recommended -- yes, information gathered,
13: yes.
14: Q. Okay. At the bottom it
15: says, "Identify high purchasing doctors.
16: Also for pain clinics, identify high
17: writing doctors in the store's area."
18: Do you see that?
19: A. Right. And I -- what I
20: don't see here is that appears to be in a
21: different shade of font, whether that was
22: a note or that was part of -- it appears
23: that these are -- there are some notes
24: that are included. There's like the

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00163

01: draft document and then there are notes.
02: Q. Well, as we discussed, there
03: was a draft and then there was going to
04: be discussion. We know that from the
05: PowerPoints that we just went over as
06: Exhibits 15 and 16, that there was a
07: discussion of these during the meeting
08: with the members, correct?
09: A. Yes.
10: Q. Page 2 of the draft has got
11: some other information. "Questionnaires
12: must be update periodically especially
13: when new areas are developed for
14: investigation."
15: Do you see that?
16: A. I do.
17: Q. That's still under the
18: heading of "know your customer," correct?
19: A. Yeah, but it also appears to
20: be in a different font or a different
21: shade of font, so...
22: Q. Okay. "Whoever completes
23: the investigation must have documented
24: formalized training."

p. 00163

00164

01: Do you see that?
02: A. I do see that.
03: Q. "Site visits should be
04: conducted when possible."
05: A. I see that, yes.
06: Q. Then it's got a Section 2
07: that is headed "Suspicious Order
08: Monitoring."
09: Do you see that?
10: A. I do.
11: Q. And then it's got a
12: background. It's got a citation to the
13: regulation.
14: Do you see that?
15: A. I do.
16: Q. And then it's got DEA
17: interpretations.
18: Do you see that?
19: A. I do.
20: Q. And move to the third page,
21: we see what those are, correct?
22: A. Yes.
23: Q. There's four discussion
24: points there, correct?

p. 00164

00165

01: A. Yes.
02: Q. So one of them is, "DEA
03: distinguishes between an order and a
04: sale. Please note in the above cited
05: regulation there is no mention of a
06: sale."
07: Do you see that?
08: A. I do.
09: Q. Agree?
10: MR. WEINSTEIN: Objection to
11: form.
12: BY MR. PIFKO:
13: Q. That's what it says?
14: A. I agree that's what it says,
15: yes.
16: Q. "DEA believes that a
17: registrant should be able to determine if
18: an order meets the above description of
19: suspicious when they receive the order,
20: not when they ship it. This is
21: particularly true for orders of unusual
22: size."
23: Agree?
24: MR. WEINSTEIN: Objection to

p. 00165

00166

01: form.
02: THE WITNESS: That's what it
03: says, yes.
04: BY MR. PIFKO:
05: Q. Okay. "DEA has indicated
06: that cutting back on an order and
07: shipping less to avoid the suspicious
08: order definition (or to meet some
09: predetermined ship limit) does not
10: relieve distributors of the
11: responsibility of reporting the order as
12: fitting the suspicious order criteria."
13: Do you see that?
14: A. I do.
15: Q. And Item 4 says, "It is
16: likely that orders deviating
17: substantially from the normal pattern and
18: orders of unusual frequency will only be
19: 'discovered by the registrant' after a
20: number of shipments have been made. DEA
21: expects shipments of such orders to be
22: stopped pending the outcome of an
23: investigation."
24: Do you see that?

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00167

01: A. I do see that.
02: Q. So you understood this as
03: documented here, were all DEA
04: interpretations of the regulation that's
05: cited above on Page 2 correct?
06: A. That's --
07: MS. ROLLINS: Object to the
08: form.
09: THE WITNESS: That's what I
10: understand.
11: BY MR. PIFKO:
12: Q. Then on Page 4, under that
13: same heading of suspicious order
14: monitoring, it's got another section,
15: "Develop 'thresholds' for suspicious
16: orders."
17: Do you see that?
18: A. I do.
19: Q. Okay. And then it's got a
20: discussion about how to calculate and
21: develop thresholds.
22: Do you see that?
23: A. Yes.
24: Q. Second paragraph says that,

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00169

01: times the average for Schedule II
02: controlled substances and reportable
03: Schedule III orders as meeting the
04: unusual threshold."
05: Is that correct, that's what
06: it says?
07: A. Yes.
08: Q. You understand C-II means
09: Schedule II controlled substance,
10: correct?
11: A. I do.
12: Q. That was a feature of this
13: draft of the guidelines, correct?
14: A. Yes.
15: MS. WICHT: Object to the
16: form of the question.
17: BY MR. PIFKO:
18: Q. Then we have Heading 3,
19: "Investigation of suspicious orders,
20: shipment decisions."
21: Do you see that?
22: A. I do.
23: Q. First discussion point there
24: it says, "Should a distributor wish to

p. 00169

00168

01: "A threshold" -- it says, "Calculate the
02: average single order and the average
03: monthly order per family, per customer,
04: and class of trade. A minimum of six
05: months' sales history or a maximum of
06: 24 months' sales history is recommended."
07: Do you see that?
08: A. I do.
09: Q. I read that correctly?
10: A. You did.
11: Q. So that's part of what is
12: being recommended for the development of
13: thresholds for suspicious orders,
14: correct?
15: MR. WEINSTEIN: Objection to
16: form.
17: THE WITNESS: In this draft,
18: yes.
19: BY MR. PIFKO:
20: Q. Okay. Then the next
21: paragraph says, "Also identify orders of
22: unusual size. It is recommended that
23: distributors follow past DEA criteria.
24: Specifically, DEA has recognized three

p. 00168

00170

01: reconsider and ship an order identified
02: as potentially suspicious or part of such
03: an order, it is recommended that he or
04: she conduct an investigation to determine
05: the reasons for the order."
06: Did I read that correct?
07: A. You did.
08: Q. And that was part of the
09: discussion of investigation and shipping
10: of potentially suspicious orders,
11: correct?
12: A. Yes.
13: Q. Then it says, "Designating
14: an investigator."
15: Do you see that?
16: A. I do.
17: Q. And then it says -- I'm
18: paraphrasing -- that the person
19: designated should have suitable
20: experience and background to be able to
21: investigate potential suspicious orders.
22: Do you see that?
23: A. Yes.
24: Q. Then it talks about the

p. 00170

00171
01: different elements of investigation on
02: Page 5.
03: Do you see that?
04: A. I do.
05: Q. One of them is to verify the
06: customer input.
07: Do you see that, at the
08: bottom of that section?
09: A. Yes.
10: Q. It says, "For example" -- it
11: says, "If the customer says they called
12: DEA, verify that they actually did so."
13: MR. WEINSTEIN: Objection to
14: form.
15: BY MR. PIFKO:
16: Q. Do you see that?
17: A. I do see that, yes.
18: Q. So verifying customer input
19: was an attribute -- an attribute of these
20: guidelines at this time, correct?
21: MS. ROLLINS: Form.
22: MR. WEINSTEIN: Objection to
23: form.
24: THE WITNESS: It says "where

p. 00171

00173
01: Q. Okay. So one is cancel the
02: order and report; one is investigate,
03: cancel, and report; another one is
04: investigate and ship, don't report; and
05: the other one is investigate, ship, and
06: report. Agree?
07: A. That's what it says, yes.
08: Q. And then there is a note
09: here. "We need to define the point when
10: the order becomes suspicious."
11: Do you see that?
12: A. Yes.
13: Q. Then there is a question
14: here. It says, "Note: Do all of the
15: options above meet DEA's regulations?"
16: Number 3: "May be
17: inconsistent with the regulations, but
18: consistent with DEA's verbal guidance."
19: Do you see that?
20: A. I do.
21: Q. And that's saying
22: investigate and ship, but don't report,
23: correct, that's Number 3 is?
24: A. That's what Number 3 is,

p. 00173

00172
01: appropriate" on the first line of
02: that. Yes, "Verify customer input
03: where appropriate. For example,"
04: and these are examples.
05: BY MR. PIFKO:
06: Q. And then there's -- at the
07: bottom of Page 5 it says, "Shipment
08: decisions. Decisions to ship an order
09: 'of interest' should be made by a person
10: specifically authorized to conduct an
11: investigation and release the order."
12: Do you see that?
13: A. I do see that.
14: Q. Then it's got, on Page 6,
15: four decision options. Do you remember
16: when we looked at the slide deck from the
17: January 31st, 2008, meeting it talked
18: about the four decisions on shipment. Do
19: you remember that?
20: A. I do.
21: Q. And so here we have the four
22: decisions on shipment.
23: Do you see that?
24: A. I do.

p. 00172

00174
01: yes.
02: Q. There's another section here
03: about filing reports with the DEA. It
04: talks about a month-end notification.
05: And then it says, "Delete this entire
06: section."
07: Agree?
08: A. That's what it says, yes.
09: Q. Okay. And as we read in the
10: other documents, an order needs to be
11: reported at the time it's identified as
12: being suspicious. That's consistent with
13: your understanding, correct?
14: MR. WEINSTEIN: Objection to
15: form, foundation, scope.
16: THE WITNESS: Again, I am
17: not sure where -- that's my
18: understanding of what they -- was
19: being discussed, yes.
20: BY MR. PIFKO:
21: Q. That is your understanding
22: of what was being discussed. I didn't
23: understand your answer.
24: A. So your question -- if you

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Page 48

00175
01: would restate the question?
02: Q. Yeah, I was -- I was saying
03: if you remember, we looked at some of the
04: other documents and they talk about how
05: you need to report an order at the time
06: you identify it as suspicious. And this
07: is saying to delete the idea of a monthly
08: notification to DEA.
09: So you agree that that's
10: consistent with the idea that you need to
11: report it when you know it, correct?
12: MR. WEINSTEIN: Objection to
13: form, foundation, and scope.
14: THE WITNESS: Again, this
15: has to do with the -- the
16: notification to DEA, month -- on a
17: monthly basis. I'm not sure that
18: refers directly to the suspicious
19: order, per se.
20: BY MR. PIFKO:
21: Q. Well, it's under the heading
22: "File Suspicious Order Reports With the
23: DEA," Section 4.
24: Do you see that?

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00177
01: MR. WEINSTEIN: Objection to
02: form.
03: THE WITNESS: Where -- which
04: section are you in?
05: BY MR. PIFKO:
06: Q. In the section --
07: A. Oh yes. In the top section,
08: yes.
09: Q. Do you see that?
10: A. "DEA office is recommending
11: to meet with the requirement to notify
12: when discovered unless DEA provides other
13: direction," yes.
14: Q. Let's go to Page 7. There
15: is a Heading 5, "Discussing Training and
16: Standard Operating Procedures."
17: Do you see that?
18: A. I do.
19: Q. And one of the things it
20: says there, at the bottom of that
21: training section is, "Training of
22: associates who are authorized to review,
23: stop, release an order, should be
24: extensive and there should be backup

p. 00177

00176
01: A. Right, but this has to do
02: with month-end DEA notification.
03: Q. Right. But it's saying to
04: delete the month-end. We're not going to
05: do that. Agree?
06: MR. WEINSTEIN: Objection to
07: form.
08: THE WITNESS: I don't know
09: that we're not going to do that.
10: It just says delete that section.
11: I don't know what that -- what
12: that meant.
13: BY MR. PIFKO:
14: Q. Well, the section above
15: says, "Immediate DEA notification."
16: Do you see that?
17: A. I do see that.
18: Q. Okay. And then it's got a
19: section under there, it says, "DEA" -- it
20: says, "To meet the requirement," it says,
21: "When discovered."
22: Do you see that in quotes?
23: MS. CHARLES: Objection to
24: form.

p. 00176

00178
01: training to cover the times when the
02: primary associate will not be available,
03: i.e., vacations, sick, et cetera?"
04: Did I read that correctly?
05: A. You did.
06: Q. And that was an attribute of
07: the -- these best practices or industry
08: compliance guidelines, correct?
09: MR. WEINSTEIN: Objection to
10: form.
11: THE WITNESS: I will note --
12: I will note that this is in a
13: different font and I'm not sure if
14: this was part of the final
15: document or not.
16: BY MR. PIFKO:
17: Q. Okay. We'll get there.
18: And then it's got additional
19: recommendations.
20: "Note: Should we also
21: consider including any or all of the
22: following?"
23: Do you see that?
24: A. I do.

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00179

01: Q. So some of these other
02: things that are being considered are
03: whether periodic audits should be
04: conducted by the independent auditor,
05: correct?
06: A. That's what it says, yes.
07: Q. Should -- should the
08: industry support a customer accreditation
09: program?
10: A. Accreditation, yes.
11: Q. Identify an individual as a
12: DEA liaison for reporting suspicious
13: orders; is that correct?
14: A. That's what it says, yes.
15: Q. Retain a list of
16: questionable registrants. Maintain a
17: list of do-not-ship accounts.
18: Do you see that?
19: A. I do see that.
20: Q. That was something that was
21: being discussed as being included?
22: A. Again, different fonts. But
23: it's part of this document, yes.
24: Q. Have you seen the final

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00181

01: BY MR. PIFKO:
02: Q. I'm handing you what's
03: marked as Exhibit 18.
04: (Document marked for
05: identification as Exhibit
06: HDA-Kelly-18.)
07: BY MR. PIFKO:
08: Q. It's a three-page document,
09: Bates labeled HDA_MDL_000217851 through
10: 853.
11: Just take a moment to review
12: this and let me know when you're done.
13: A. Okay.
14: Q. If you recall from
15: Exhibit 14, we talked about how the
16: consultant and Ms. Ducca worked on the
17: draft, correct?
18: A. Yes.
19: Q. And here in Exhibit 18,
20: Mr. Wilson, on February 6, 2008, is
21: sending her what he calls a discussion
22: intro, in the subject of the e-mail.
23: And he says, "Here is the
24: discussion header. I used the same

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00180

01: industry compliance guidelines?
02: A. Yes.
03: Q. So the document we just
04: discussed, Exhibit 17, it's just the
05: nitty-gritty, the details of the
06: guidelines, correct?
07: MR. WEINSTEIN: Objection to
08: form.
09: THE WITNESS: It's labeled
10: as a discussion draft.
11: BY MR. PIFKO:
12: Q. All I'm getting at is,
13: the -- the final draft has some
14: introductory explanatory language,
15: correct, the background about them,
16: correct, that's not in the discussion
17: draft, right?
18: A. Yes. There's addition --
19: and, again, I'm not sure what made it
20: from the discussion draft into the final
21: draft unless I was able to compare them
22: next to one another.
23: MS. CHARLES: Object to the
24: form of that question.

p. 00180

00182

01: language you did on the draft. I will
02: call you tomorrow around 9:00 a.m. your
03: time."
04: Do you see that?
05: A. Yes.
06: Q. So he's sending her some
07: language that they discussed together,
08: agree?
09: MR. WEINSTEIN: Objection to
10: form.
11: THE WITNESS: Again, yes.
12: BY MR. PIFKO:
13: Q. And so as we discussed,
14: the -- the final draft has some
15: background language, history, et cetera,
16: correct?
17: A. It does.
18: Q. Okay. And so this is a
19: first draft of that, it says, if you look
20: on the second page, first draft.
21: Do you see that?
22: A. I see that.
23: Q. And then it's got a heading
24: history. And it talks about 1970

p. 00182

00183

01: Congress enacted the Controlled
02: Substances Act.
03: Do you see that?
04: A. Yes.
05: Q. Okay. At the bottom of that
06: page there's a section here, it says, "Up
07: until now, DEA has interpreted this
08: section to require distributors to design
09: and operate a system to identify and
10: report suspicious orders, based on the
11: regulation's definition of suspicious."
12: Did I read that correctly?
13: A. You did.
14: Q. The next page says,
15: "Recently, and without any due process
16: for rule changes, DEA has expanded the
17: definition of suspicious orders to
18: include those that the registrant may
19: have reason to believe the order will be
20: diverted."
21: Do you see that?
22: A. I do.
23: Q. Did I read that correctly?
24: A. You did.

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00185

01: says, "DEA seems to have taken the
02: position that if the registrant did not
03: know their customer was diverting,
04: they" -- in all caps -- "should have
05: known and have attached severe penalties
06: to not knowing. That is the purpose of
07: the following discussion points regarding
08: knowing your customer, identifying and
09: reporting suspicious order of controlled
10: substances, and training everyone who
11: comes into contact with controlled
12: substances."
13: Did I read that correctly?
14: A. You did.
15: Q. So at this time you agree
16: that it's saying the discussion points,
17: the attributes that we discussed in the
18: prior draft, those are all designed at
19: this idea of addressing the DEA's concern
20: that registrants should know if their
21: customers are diverting controlled
22: substances, correct?
23: MR. WEINSTEIN: Objection to
24: form, foundation, and scope.

p. 00185

00184

01: Q. Then it says, "In three
02: public statements to congressional
03: committees on December 13, 2005; July 26,
04: 2006; and September 18, 2007, the DEA
05: administrator has spoken about, quote,
06: the growing problem of diversion and
07: abuse of controlled pharmaceuticals
08: continues to be one of the top priorities
09: of the Drug Enforcement Administration."
10: "We have also used our
11: regulatory authority to take action
12: against DEA registrants found to be in
13: violation of regulatory requirements
14: under the Controlled Substance Act.
15: "Through regulatory
16: authority, DEA has subjected registrants
17: to significant civil fines, licensing
18: restrictions or even suspended
19: registration. Such civil remedies have
20: proven to be an effective deterrent to
21: potential violators."
22: Did I read that correctly?
23: A. You did.
24: Q. And then the last paragraph

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00186

01: THE WITNESS: That's
02: correct. That's what I understand
03: it to mean, yes.
04: (Document marked for
05: identification as Exhibit
06: HDA-Kelly-19.)
07: BY MR. PIFKO:
08: Q. I'm handing you what's
09: marked as Exhibit 19. This is another
10: e-mail from Ms. Ducca Bates-labeled
11: HDA_MDL_000148603 to 148633.
12: Take a moment to review it.
13: It attaches a revised draft of the
14: document we looked at in Exhibit 17.
15: MR. STEWART: Can we take a
16: break while he reads the document?
17: BY MR. PIFKO:
18: Q. I think he's done.
19: A. Yeah, I was trying to
20: determine what the -- so this is the
21: accepted changes versus --
22: Q. I'll walk you -- I'll walk
23: you through it here.
24: A. Okay.

p. 00186

00187

01: Q. Okay. So if you'll recall
02: in Exhibit 14, Ms. Ducca talks about
03: scheduling call February 7th to have a
04: further discussion about the guidelines.
05: Do you see that? Or do you
06: recall that?
07: And then this Exhibit 19 is
08: her sending out attachments for this call
09: that's going to happen on February 7th,
10: agree?
11: A. Yes.
12: Q. And what we're seeing here
13: is a red line against the version that we
14: reviewed in Exhibit 17. That's actually
15: a clean version she attaches, and a red
16: line version. The red line starts at
17: 148619, agree?
18: A. Yes.
19: Q. Okay. So then, you see this
20: draft, it's -- the heading on this draft
21: is Version 8, post 1/31/08. This is
22: distinguishing that it's after that
23: January 31, 2008, meeting, correct?
24: A. Yes.

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00188

01: Q. And now this draft has some
02: of the introductory background language
03: that we discussed in Exhibit 18, correct?
04: A. Yes, with the addition of
05: some additional information.
06: Q. Right. So not all of the
07: language that we discussed in Exhibit 18
08: made it into this draft, correct?
09: A. That's -- yes, from what I
10: could tell.
11: Q. For example, there was that
12: paragraph, "Up until now DEA has
13: interpreted this section that required
14: distributors to design and operate a
15: system to identify and report suspicious
16: orders."
17: Do you remember that
18: discussion? That's not in here, correct?
19: A. What -- what version are you
20: looking at?
21: Q. If you have -- if you want
22: to open Exhibit 18 up --
23: A. Okay. I'm sorry.
24: Q. -- and compare it to what

p. 00188

00189

01: you're seeing in the introduction and
02: history section in Exhibit 19. That
03: paragraph is not in there, correct?
04: A. It does not appear to be.
05: Q. And then the section,
06: "Recently, without any due process for
07: rule changes," that whole paragraph in
08: Exhibit 18 isn't in here either, correct?
09: It's not in Exhibit 19, correct?
10: A. It does not appear to be.
11: Q. Okay. And so let's look at
12: some of the language that's added here
13: from the January 31st, 2008, draft that
14: we reviewed in Exhibit 17.
15: First, in the introduction.
16: Let me know when you're there.
17: A. We're on the second --
18: Q. If you want to use the red
19: line, you can, which starts on 148619.
20: A. Okay.
21: Q. Are you there?
22: A. I -- yes.
23: Q. This allows us to see what's
24: added from the prior draft that was in

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00190

01: Exhibit 17, agree?
02: A. Yes.
03: Q. And so all of this language,
04: the introduction, history, distribution
05: industry, commitment to securing the
06: supply of controlled substances, that's
07: all new, correct?
08: A. From the version in 17?
09: Q. Yeah.
10: A. Exhibit 17? Yes.
11: Q. Okay. And so one of the
12: things in the first paragraph, it says,
13: is that, at the bottom of that first full
14: paragraph, it's talking about these
15: guidelines. It says, "They have been
16: prepared in recognition of the growing
17: problem of misuse of controlled
18: substances and the key role distributors
19: play within the prescription drug supply
20: chain."
21: Did I read that correctly?
22: A. You did.
23: Q. Okay. And so is that
24: consistent with what your understanding

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00191
01: of the background of how these were
02: prepared?
03: MR. WEINSTEIN: Objection to
04: form.
05: THE WITNESS: Yes, that's
06: what I understand it to be.
07: BY MR. PIFKO:
08: Q. And HDMA and its members
09: recognized that there was a growing
10: problem of misuse of controlled
11: substances at this time?
12: MR. WEINSTEIN: Objection to
13: form. Foundation. Scope.
14: THE WITNESS: That's what we
15: stated here in this introduction.
16: BY MR. PIFKO:
17: Q. And the role -- and the key
18: role that distributors play within the
19: prescription drug supply chain, correct?
20: MR. WEINSTEIN: Same
21: objections.
22: THE WITNESS: Again, it's
23: stated here in the introduction.
24: BY MR. PIFKO:

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00193
01: level of assurance that those who
02: purchase controlled substances from
03: wholesale distributors intend them to be
04: used for legitimate and legally
05: acceptable patient needs."
06: Did I read that correctly?
07: A. You did.
08: Q. "In other words, with such
09: due diligence, it is possible to reduce
10: the probability that controlled
11: substances will reach locations within
12: the supply chain for which they are not
13: intended."
14: Did I read that correctly?
15: A. You did.
16: Q. And so HDMA and its members
17: recognized this to be true at this time
18: as well, correct?
19: MR. WEINSTEIN: Objection to
20: form, foundation, scope.
21: THE WITNESS: It's what's
22: stipulated here in this
23: introduction, yes.
24: BY MR. PIFKO:

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00192
01: Q. And then in the next
02: paragraph it says, "While drug wholesale
03: distributors, like all nongovernmental
04: entities, do not have investigative
05: powers and resources to guarantee that
06: certain products will not reach illicit
07: or illegal markets, they are uniquely
08: situated to perform due diligence in
09: order to help support the security of the
10: controlled substances distribution
11: system."
12: Did I read that correctly?
13: A. You did.
14: Q. That was another thing that
15: HDA and its members recognized at this
16: time, correct?
17: MR. WEINSTEIN: Objection to
18: form. Foundation. Scope.
19: THE WITNESS: And included
20: it in this introduction, yes.
21: BY MR. PIFKO:
22: Q. It then says, "Rigorous" --
23: in the next paragraph, "Rigorous due
24: diligence can aid in providing a greater

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00194
01: Q. So let's go to the second
02: page. There's a heading, "Distribution
03: Industry Commitment to Securing the
04: Supply of Controlled Substances."
05: Do you see that?
06: A. I do.
07: Q. It says in that paragraph,
08: partway through the first sentence,
09: "Recent concerns about the potential
10: misuse of controlled substances has
11: elevated their awareness and that of the
12: DEA and the public, to the need for
13: greater rigor in evaluating the purchase
14: orders of such" -- "for such products."
15: Did I read that correctly?
16: A. Yes.
17: MS. MACKAY: Object to the
18: form.
19: BY MR. PIFKO:
20: Q. And the HDA and its members
21: understood that to be true at this time,
22: correct?
23: MR. WEINSTEIN: Objection to
24: form, foundation, and scope.

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00195
01: THE WITNESS: That's what's
02: stated here in this document, yes.
03: BY MR. PIFKO:
04: Q. Then in the next paragraph
05: it says, second sentence, "We are
06: confident that implementation of these
07: guidelines will aid in the appropriate
08: distribution of controlled substances to
09: supply chain partners involved in the
10: legitimate dispensing of these important
11: products to patients they serve."
12: Did I read that correctly?
13: A. You did.
14: Q. And HDMA and its members
15: understood that to be true at this time,
16: correct?
17: MR. CRAWFORD: Objection to
18: form.
19: MR. WEINSTEIN: Objection to
20: form, foundation, and scope.
21: THE WITNESS: They
22: understood that -- that these were
23: guidelines that could help in
24: addressing prescription drug

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00197
01: there.
02: A. Page 7? I'm there.
03: Q. Yeah, okay. And it's got
04: two options.
05: Do you see that?
06: A. I do.
07: Q. And it's talking about
08: whether, if there's a suspicious order, a
09: distributor should stop the whole order
10: or they could ship a portion of the
11: order. Do you agree that's what it's
12: discussing.
13: MS. ROLLINS: Object to the
14: form.
15: THE WITNESS: Where -- where
16: are you reading?
17: BY MR. PIFKO:
18: Q. Well, there's two options
19: Option 1 stop shipments of the individual
20: drug code product that is an order of
21: interest.
22: A. I see that, yes.
23: Q. Or then it's saying
24: Option 2: "Distributors may ship a

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00196
01: diversion, yes.
02: BY MR. PIFKO:
03: Q. And HDMA and its members put
04: this -- this language together, correct?
05: MR. WEINSTEIN: Objection to
06: form.
07: THE WITNESS: HDMA and its
08: distributor members, yes.
09: BY MR. PIFKO:
10: Q. And all the language we've
11: been discussing, correct?
12: MR. WEINSTEIN: Objection to
13: form.
14: MS. MACKAY: Foundation.
15: THE WITNESS: Yes, the
16: language that is before us, that
17: we're looking at is prepared by
18: HDMA and HDMA member companies,
19: distributor member companies.
20: BY MR. PIFKO:
21: Q. There's another section a
22: few pages in, "Stop Shipments of an Order
23: of Interest."
24: Let me know when you're

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00198
01: portion of the entire individual drug
02: code product that is an order of
03: interest."
04: Do you see that?
05: A. I do see that, yes.
06: Q. So there was a discussion at
07: this time as to which of those options
08: was going to be included in this -- into
09: the final draft, correct?
10: MS. CHARLES: Objection to
11: form.
12: THE WITNESS: I don't
13: know -- I don't know what the
14: intention was for including the
15: options, if that was a discussion
16: about including one or the other
17: or leaving both.
18: MR. WEINSTEIN: Mark, we've
19: been going about an hour and a
20: half. If there's a good point
21: for --
22: MR. PIFKO: Yeah, let me
23: just hand him this exhibit. I'm
24: just going to address that topic

p. 00198

00199

01: and then we can take a break.
02: MR. WEINSTEIN: A few more
03: minutes?
04: THE WITNESS: Yep.
05: (Document marked for
06: identification as Exhibit
07: HDA-Kelly-20.)
08: BY MR. PIFKO:
09: Q. I'm handing you what's
10: marked as Exhibit 20. For the record,
11: it's a document Bates-labeled
12: HDA_MDL_000213058 through 213077. It's a
13: PowerPoint from the HDA government public
14: policy council dated February 12, 2008,
15: titled, "HDMA-DEA Suspicious Orders 'best
16: Practices.'"
17: Let me know when you are
18: ready.
19: A. Okay.
20: Q. So you recall when we first
21: discussed the hiring of Mr. Wilson and
22: the decision that HDMA was going to put
23: out these best practices, that ultimately
24: they have to get approved by the board,

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00201

01: Q. Then we see a calendar on
02: Slide 3 that's got the different events.
03: This is consistent with what we've been
04: discussing and your understanding of the
05: process, correct?
06: There was a meeting on
07: January 31, 2008, and we looked at --
08: Exhibit 19 was the revised draft provided
09: to the regulatory affairs committee on
10: February 7th for them to review. Here
11: it's got the 8th.
12: And then this is -- this
13: meeting on February 12, 2008, for the
14: government public policy council to
15: review?
16: A. Yes.
17: Q. Agree?
18: A. Yes.
19: Q. Some of these slides are
20: similar to the presentation we saw on --
21: on January 31st that we went over on
22: Exhibit 16, correct?
23: MS. CHARLES: Object to the
24: form.

p. 00201

00200

01: correct?
02: A. That's correct.
03: Q. And so this is a meeting
04: that's discussing getting to --
05: ultimately getting to approval of the
06: guidelines, correct?
07: A. Correct.
08: Q. And we see on the second
09: page it says agree -- "Goals: Agree upon
10: final draft of best practices for
11: executive committee review."
12: Do you see that?
13: A. Yes.
14: Q. And then it says, "Resolve
15: partial shipment issue."
16: Do you see that?
17: A. Yes.
18: Q. And that's the issue we were
19: discussing in Exhibit 19 where there's
20: the two options. Agree?
21: MS. CHARLES: Objection to
22: form.
23: THE WITNESS: Yes.
24: BY MR. PIFKO:

p. 00200

00202

01: THE WITNESS: Yeah, I
02: don't -- I don't believe there was
03: a timeline, but yes, similar in
04: scope. Yes.
05: BY MR. PIFKO:
06: Q. Discussion of legal -- yeah,
07: there's like just legal discussions about
08: the requirements and the Rannazzisi
09: letters. Agree?
10: A. Agree.
11: MS. ROLLINS: Objection to
12: form.
13: BY MR. PIFKO:
14: Q. Okay. So then I want to
15: direct your attention to Slide 11, it's a
16: slide headed "Next Steps."
17: Do you see that?
18: A. I do.
19: Q. So second bullet point --
20: well, first bullet point is that the
21: executive committee is going to review
22: them on February 22nd, agree?
23: A. Yes.
24: Q. And then another next step

p. 00202

00203

01: is that we're going to continue pharmacy
02: association/pain coalition discussions,
03: agree?
04: A. That's what it says, yes.
05: Q. And so there was going to be
06: an effort to continue discussing these
07: with the Pain Care Foundation as we
08: discussed before, correct?
09: MR. WEINSTEIN: Objection to
10: form.
11: MS. CHARLES: Objection to
12: form.
13: MR. WEINSTEIN: Foundation.
14: THE WITNESS: That's what it
15: says, yes.
16: BY MR. PIFKO:
17: Q. Do you have any reason to
18: dispute that it happened?
19: A. I do not.
20: Q. Then another next step is
21: going to request a meeting with the DEA
22: acting administrator. You recall that we
23: discussed that when we first looked at
24: the scope of work for this, correct?

p. 00203

00204

01: A. Yes.
02: Q. And then one point of
03: discussion was to request DEA endorsement
04: of the best practices as a safe harbor.
05: Do you see that?
06: A. I do.
07: Q. You understood that there
08: was going to be a request to the DEA that
09: if people implemented these, they would
10: have a safe harbor with respect to
11: diversion control compliance?
12: MS. MACKAY: Objection to
13: form.
14: THE WITNESS: Again, I
15: think -- I think -- yeah, the
16: concept was to basically broach
17: these as a potential solution to
18: due diligence under the
19: expectations of DEA. I don't know
20: if we officially requested their
21: endorsement. We did show them the
22: completed guidelines.
23: BY MR. PIFKO:
24: Q. In addition to due

p. 00204

00205

01: diligence, know your customer and not
02: shipping suspicious orders, correct?
03: MR. WEINSTEIN: Objection to
04: form.
05: MS. ROLLINS: Objection to
06: form.
07: THE WITNESS: I'm sorry.
08: With --
09: BY MR. PIFKO:
10: Q. With respect to -- you said,
11: "The concept was basically to broach
12: these as a potential solution to due
13: diligence." But I'm saying, also know
14: your customer and the idea of not
15: shipping suspicious orders, correct?
16: A. Right. That would all be
17: included in due diligence, yes.
18: Q. Okay. Slide 16. It's got
19: some key points from the January 31st
20: meeting. Are you there?
21: A. I am.
22: Q. Okay. First one is -- it
23: says that, "Implementing the best
24: practices will expand distributors'

p. 00205

00206

01: efforts considerably." And considerably
02: is in italics.
03: Do you see that?
04: A. I do.
05: Q. Okay. So if you were going
06: to implement these, it would be a
07: considerable effort, correct?
08: MR. WEINSTEIN: Objection to
09: form. Foundation.
10: THE WITNESS: It would be --
11: yes. That's what I understand it
12: to mean.
13: BY MR. PIFKO:
14: Q. And then it says,
15: "Inevitably impacts customers, may be
16: significant."
17: Do you see that?
18: A. I do see that.
19: Q. So there could be a
20: significant impact on customers from
21: implementing these, correct?
22: MR. WEINSTEIN: Objection to
23: form. Foundation. Scope.
24: THE WITNESS: That's what I

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00207
01: understand it to mean, yes.
02: BY MR. PIFKO:
03: Q. And go to Slide 17. This is
04: a discussion of that partial shipment
05: option that we looked at that was in the
06: draft in Exhibit 19, agree?
07: A. Yes.
08: Q. And so it's got some -- it
09: identifies the issue of what should be
10: done. And then it's got voting, agree?
11: MS. CHARLES: Objection to
12: form.
13: THE WITNESS: That's, I
14: guess, what it appears to have.
15: I'm not sure if that's voting
16: within the regulatory affairs
17: committee.
18: BY MR. PIFKO:
19: Q. But there's some voting, by
20: some constituent within HDA, correct?
21: A. This appears to indicate
22: that, yes.
23: MS. CHARLES: Objection to
24: form.

p. 00207

00209
01: form. Foundation.
02: THE WITNESS: That's what it
03: says, yes.
04: BY MR. PIFKO:
05: Q. A con is that DEA
06: correspondence/interpretation is do not
07: support this practice, agree?
08: MR. WEINSTEIN: Objection to
09: form.
10: THE WITNESS: That's what it
11: says, yes.
12: MR. PIFKO: We can take a
13: break.
14: THE VIDEOGRAPHER: The time
15: is 12:06 p.m. We are going off
16: the record.
17: - - -
18: (Lunch break.)
19: - - -
20: A F T E R N O O N S E S S I O N
21: - - -
22: THE VIDEOGRAPHER: The time
23: is 12:44 p.m. We are back on the
24: record.

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00208
01: BY MR. PIFKO:
02: Q. And it says, "If a specific
03: drug code product order is potentially
04: suspicious, should the distributor be
05: able to ship part of the order for that
06: particular product prior to further
07: evaluation?"
08: That's what it says,
09: correct?
10: A. That's what it says, yes.
11: Q. And then it says seven are
12: in favor, three opposed, one abstained,
13: and one was absent, agree?
14: A. That's what it says.
15: MR. WEINSTEIN: Objection to
16: form.
17: BY MR. PIFKO:
18: Q. And then it's got pros and
19: cons of adopting that approach, agree?
20: A. That's what it lists, yes.
21: Q. One of the pros is it's
22: consistent with the current practice for
23: many distributors, agree?
24: MR. WEINSTEIN: Objection to

p. 00208

00210
01: - - -
02: EXAMINATION (Cont'd.)
03: - - -
04: BY MR. PIFKO:
05: Q. I'm handing you what's
06: marked as Exhibit 21.
07: (Document marked for
08: identification as Exhibit
09: HDA-Kelly-21.)
10: BY MR. PIFKO:
11: Q. It's another series of
12: e-mails from Anita Ducca dated March 4th,
13: 2008, attaching another version of the
14: guidelines, Bates-labeled
15: CAH_MDL2804_01521412 through 1469.
16: There's another red line of
17: this draft against the draft that we
18: looked at in Exhibit 19. I'm not going
19: to ask you any questions about it. But
20: you can review it. But in the interest
21: of time, I was just want to direct your
22: attention to the first page of
23: Exhibit 21.
24: A. That's all we're going to

p. 00210
Page 57

00211
01: be?
02: Q. Yeah.
03: A. Do you want me to read the
04: back end of it?
05: Q. Sure. I'm not going to ask
06: you about that either. Just the e-mail
07: on the front.
08: A. I've read the top sheet.
09: Q. Okay. So Exhibit 21 is
10: Anita Ducca sending to the regulatory
11: affairs committee members another draft
12: of the suspicious orders best practices,
13: agree?
14: MR. WEINSTEIN: Objection to
15: form.
16: THE WITNESS: Yes. I think
17: that's -- that's what it entails.
18: And with kind of a changing of the
19: name to the practice guidelines,
20: which was not the final name of
21: the document, but...
22: BY MR. PIFKO:
23: Q. Right, so she says, "I've
24: attached a copy of the very latest

p. 00211

00213
01: know that they were vetted with various
02: external groups to determine how they
03: should be named and packaged and
04: presented.
05: Q. Do you know what other
06: external groups?
07: A. Other than -- I mean,
08: external groups as far as within the
09: organization. So our government affairs
10: committees, our communications
11: committees, legal counsel, outside
12: counsel.
13: Q. And so this says, "Change
14: them to recommended practice guidelines,"
15: but ultimately they ended up being called
16: industry compliance guidelines, correct?
17: A. Correct.
18: Q. Do you know if there were
19: any other iterations of what they would
20: be called in between this and the final
21: name?
22: A. I -- I do not know. I
23: think -- again, I think the practice -- I
24: mean I think we wanted to stay away from

p. 00213

00212
01: version of the draft suspicious order
02: practices. The executive committee
03: approved these."
04: Do you see that?
05: A. Yes.
06: Q. The executive committee
07: approved the draft she attaches in this
08: document, correct?
09: A. That's what I understand it
10: to mean, yes.
11: Q. And then it says, "Also, we
12: have made some changes, mostly regarding
13: wording and formatting and included
14: recommendations by our outside counsel
15: and our communications department,
16: including a suggestion to re-name them
17: 'recommended practice guidelines.'"
18: Do you see that?
19: A. I do.
20: Q. So the outside counsel or
21: communications department recommended
22: that you re-name them?
23: A. Again, I don't know who
24: recommended exactly renaming them. I do

p. 00212

00214
01: basically establishing anything that said
02: best practices or standards because we
03: are not a standard setting organization.
04: We can't compel our members
05: to, you know, adopt these best practices,
06: per se. So they are guidelines. They
07: are voluntary guidelines.
08: Q. So then, this also talks
09: about how there's going to be a meeting
10: with Mark Caverly. He's from the DEA,
11: correct?
12: A. Correct.
13: Q. And again, this is
14: consistent with the overall strategy that
15: we saw in the earlier documents that was
16: designed in 2007 where you're going to
17: draft these, get industry to all agree on
18: the language, and then have a meeting
19: with DEA to discuss them, correct?
20: MR. WEINSTEIN: Objection to
21: form.
22: THE WITNESS: Again, get
23: our -- get our members that were
24: participating in that process to

p. 00214

00215

01: agree on them. And then basically
02: vet them with the DEA to see if
03: they had any concerns with the
04: scope of the -- of the guidelines.
05: (Document marked for
06: identification as Exhibit
07: HDA-Kelly-22.)
08: BY MR. PIFKO:
09: Q. I'm handing you what's
10: marked as Exhibit 22. It's an e-mail
11: from HDA's Kristen Freitas dated
12: Thursday, March 20, 2008. Due to some
13: sort of way the document was produced,
14: there's a lot of gibberish and blank
15: pages, but the substance can be distilled
16: down to four pages.
17: But for the record, it's
18: Bates-labeled ANDA_OPIOIDS_MDL_0000157358
19: to 157473.
20: For the record, take a
21: minute to review it and let me know when
22: you're done.
23: The substantive discussion
24: starts at 157380, it ends at 83. I think

p. 00215

00217

01: that's under your purview in your current
02: position?
03: A. It is.
04: Q. Okay. So Kristen Freitas
05: reports to you?
06: A. Up through me, yes. I'm the
07: head of the department. She reports
08: directly to our general counsel.
09: Q. Okay. So at this time,
10: she's talking about some other aspects of
11: the strategy to, as we talked about in
12: Exhibit 3, address the executive
13: committee's concerns about recent DEA
14: activities to involve wholesale
15: distributors in efforts to prevent
16: diversion. Agree?
17: MR. WEINSTEIN: Objection to
18: form.
19: THE WITNESS: I'm sorry. So
20: you -- you --
21: BY MR. PIFKO:
22: Q. This is a furtherance of the
23: overall strategy that we talked about
24: that was starting to be implemented in

p. 00217

00216

01: that's where you were.
02: A. 8383?
03: Q. Yeah.
04: A. 157383? Okay.
05: Q. So my first question is, who
06: is Kristen Freitas?
07: A. Kristen Freitas is currently
08: now the vice president of federal
09: government affairs for HDA, then HDMA.
10: She was then probably a manager or a
11: director.
12: Q. It says here on her
13: signature on the second page, associate
14: director.
15: A. Associate director.
16: Q. What's federal government
17: affairs do?
18: A. Federal government affairs
19: is tasked primarily with the interface
20: with Congress. The HDA segment of the
21: government affairs department that deals
22: directly with Congress, anything that
23: happens on the Hill.
24: Q. Is that a -- something

p. 00216

00218

01: Exhibit 3, which derives from the
02: executive committee's concerns about
03: recent DEA activities to involve
04: wholesale distributors in efforts to
05: prevent diversion. Do you agree?
06: MR. WEINSTEIN: Objection to
07: form.
08: THE WITNESS: That should --
09: yes. I would agree it is part of
10: that process.
11: BY MR. PIFKO:
12: Q. Okay. So then she says
13: here, "DEA - as we discussed on the
14: federal government affairs committee call
15: on Monday, HDMA staff have developed a
16: confidential draft political strategy to
17: address some of the issues related to DEA
18: and suspicious orders. As the document
19: states, many of the tactics and messaging
20: hinge on the outcome of the DEA meeting
21: where we will" -- "we will present our
22: recommended industry compliance
23: guideline."
24: Did I read that correctly?

p. 00218

00219

01: A. You did.
02: Q. Okay. So it was understood
03: within HDA and its members that,
04: depending on this meeting where the
05: guidelines were shared with the DEA, that
06: would shape how further strategies were
07: implemented, agree?
08: MR. WEINSTEIN: Objection to
09: form. Foundation.
10: THE WITNESS: I would agree,
11: yes.
12: BY MR. PIFKO:
13: Q. So then we see, if you go to
14: 157380, there's a discussion of various
15: tactics that are going to be part of "the
16: HDMA Hill DEA strategy."
17: Do you see that?
18: A. I do.
19: Q. Okay. Tactic Number 1 is,
20: "Complete and present recommended
21: industry compliance guidelines to DEA
22: general counsel."
23: Do you see that?
24: A. Yes.

p. 00219

00221

01: A. Again, I think it had to do
02: with, and the timing of this would have
03: been -- if this is after the -- the
04: hearing. This was on March 20th.
05: Again, I think it was
06: basically when FDA or DEA on an annual
07: basis goes before the appropriation
08: committee to discuss their budget, that
09: if there were concerns or questions about
10: their perspective on our guidelines or
11: their suspicious order monitoring
12: tactics, that we provide some feedback to
13: the appropriation members so they could
14: ask for further clarification from the
15: administrator while she was there
16: testifying.
17: Q. Okay. And so you drafted,
18: on behalf of your members, potential
19: questions to be asked by members of
20: Congress to ask the DEA, correct?
21: MR. WEINSTEIN: Objection to
22: form.
23: THE WITNESS: That's what I
24: understand these to be, yes.

p. 00221

00220

01: Q. Okay. You agree that's the
02: first tactic mentioned here?
03: A. That is, yes.
04: Q. And then it says, "Status:
05: Request to be made the week of
06: March 17th."
07: Agree?
08: A. That's what it says, yes.
09: Q. And like we just saw in the
10: prior department, "The discussion and
11: outcome of this meeting will be critical
12: in driving all further tactics and
13: messaging."
14: Agree?
15: A. That's what it says, yes.
16: Q. Then it says, "Brief House
17: appropriation subcommittee members who
18: participated in the March 12th DEA budget
19: justification hearing. Seek questions to
20: be asked for the record."
21: Do you see that?
22: A. Yes.
23: Q. Do you have an understanding
24: about what that was about?

p. 00220

00222

01: BY MR. PIFKO:
02: Q. And that starts on 157382
03: and goes to 383, correct?
04: A. Correct.
05: Q. Okay. Tactic 3 is, "Brief
06: Senate appropriation subcommittee members
07: in advance of DEA budget justification
08: hearing. Seek commitment to ask
09: questions of DEA administrator."
10: Do you see that?
11: A. Yes.
12: Q. Do you have an understanding
13: what that's about?
14: A. Again, similar to what was
15: done on the House side. But again maybe
16: those questions were developed for the
17: Senate side, because it appears that this
18: e-mail was sent after the 3/12
19: appropriations committee.
20: Q. Okay. So these questions
21: are for senators to ask the DEA?
22: A. I would deduce that
23: that's -- yes, that's the process.
24: Q. And that's a common tactic

p. 00222

00223

01: that you use in the organization, is to
02: draft questions for senators or members
03: of Congress to ask DEA if you have
04: concerns?

05: MR. WEINSTEIN: Objection to
06: form.

07: THE WITNESS: That is a
08: common practice for a lot of
09: associations that interact with
10: regulatory authorities.
11: BY MR. PIFKO:

12: Q. Including HDA?

13: A. In this instance including
14: HDA.

15: Q. And so when it says, "Brief
16: senate appropriation subcommittees in
17: advance of the hearing," there's also
18: one-on-one meetings that occur with the
19: senators in advance of the hearing?

20: MR. WEINSTEIN: Objection to
21: form. Foundation.

22: THE WITNESS: I would
23: imagine these are primarily
24: meetings with staff,

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00225

01: your views and provide potential

02: questions?

03: A. Correct.

04: MR. WEINSTEIN: Objection to
05: form.

06: THE WITNESS: Sorry.

07: BY MR. PIFKO:

08: Q. Go a few more tactics down.

09: Number 6, it says, "Educate and seek

10: advocates for HDMA among pain community

11: who will assist in delivering our message

12: to Hill."

13: Do you see that?

14: A. I do.

15: Q. So you were going to, as

16: part of this effort, you were going to

17: also enlist others in the pain community

18: to communicate your message to lawmakers;

19: that's correct?

20: MS. CHARLES: Objection to

21: form.

22: THE WITNESS: That's what

23: this indicates.

24: BY MR. PIFKO:

p. 00225

00224

01: staff-to-staff meetings. Seldom
02: to the member representatives
03: participate in those meetings. So
04: these are staff briefings.

05: BY MR. PIFKO:

06: Q. That's where the questions
07: are provided?

08: MR. WEINSTEIN: Objection to
09: form. Foundation.

10: THE WITNESS: Again, that's

11: where I -- if they were provided,

12: again, I don't know what was

13: provided. This was looking at a

14: draft document of some kind. I am

15: not sure which specific questions

16: were provided or if any of the

17: questions were provided.

18: BY MR. PIFKO:

19: Q. Okay. But in your ordinary

20: practice as part of your lobbying

21: efforts, that's how questions would be

22: provided, you would have your staff

23: members meet with lawmakers' staff

24: members and that's when you would discuss

p. 00224

00226

01: Q. And then it says, "Status,

02: HDMA joined and briefed the Pain Care

03: Forum, an informal coalition of

04: pharmaceutical companies and patient

05: advocacy groups focusing on pain

06: management issues and will follow up upon

07: release of our industry compliance

08: guidelines."

09: Did I read that correctly?

10: A. You did.

11: Q. Okay. And so that confirms

12: HDMA did join the Pain Care Forum,

13: correct?

14: A. Yes. In 2008.

15: Q. And you briefed them on

16: these issues, correct?

17: MS. MACKAY: Objection to

18: form.

19: THE WITNESS: Again, this

20: seems to indicate that we briefed

21: them that we were developing the

22: industry compliance guidelines

23: just to give them a heads-up. And

24: we were indicating to this, we

p. 00226

00227

01: would share our final document
02: when it was developed and
03: released.
04: BY MR. PIFKO:
05: Q. And then you sought their
06: contribution to also advocate to members
07: on the Hill, correct?
08: MR. WEINSTEIN: Objection to
09: form.
10: THE WITNESS: Again I don't
11: know what the specific ask was.
12: This was an informal kind of
13: coalition group, and we were
14: briefing them on what we were
15: doing. This seems to indicate
16: that we were -- educate and seek
17: advocates for HDMA among pain
18: community who will assist in
19: delivering our message on the
20: Hill. So yes, it appears that we
21: were asking them to support our
22: industry compliance guidelines.
23: BY MR. PIFKO:
24: Q. And then Number 8 says,

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00229

01: we were trying to basically convey
02: in some of the questions that were
03: put together. So we were -- yeah,
04: we were seeking greater clarity
05: from the agency and it was not
06: forthcoming, and so we were
07: requesting that our congressional
08: colleagues possibly request a
09: meeting so we could convey those
10: concerns.
11: BY MR. PIFKO:
12: Q. When I handed you this
13: document, you read it in its entirety,
14: correct?
15: A. The document that I'm
16: looking at right now?
17: Q. Yeah. We took a moment and
18: you were reading it?
19: A. Yeah, I read -- yes, the
20: pages that you referenced, yes.
21: Q. You read the questions --
22: potential Hill questions for DEA, right?
23: A. I did, yes.
24: Q. Okay. And so the thrust of

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00228

01: "Identify high-level congressional
02: 'champion' who will request a meeting
03: with DEA to discuss concerns with current
04: tactics."
05: Do you see that?
06: A. I do.
07: Q. Do you have an understanding
08: about what that's about?
09: A. Again, what it says. So
10: probably ask a member of Congress,
11: possibly a high-level senior ranking
12: official or a ranking member in their
13: party to request a meeting with DEA,
14: possibly a committee chairman of some
15: kind, a relevant committee.
16: Q. And so at this time HDMA and
17: its members were concerned with the
18: enforcement tactics being used by the
19: DEA, correct?
20: MR. WEINSTEIN: Objection to
21: form.
22: THE WITNESS: I think -- I
23: think there was concern about the
24: lack of clarity and basically what

p. 00228

00230

01: the questions, you know, goes at the end
02: here. It says, if you look on 157382,
03: "Isn't your initiative overly broad and
04: not focused specifically enough on rogue
05: pharmacies, which in fact make up a
06: miniscule percentage of any legitimate
07: wholesaler's business?"
08: And then it says, "Clearly,
09: if a customer is known to be diverting
10: prescription drugs and the wholesale
11: distributor continues to supply that
12: customer, a violation of their registrant
13: responsibilities as has occurred. But my
14: concern here is that your expectations go
15: to a much higher level, asking the
16: wholesaler in essence to be your
17: investigator. I don't think that's
18: appropriate. It seems to me at the end
19: of the day that prescription drug abuse
20: is caused by inappropriate prescribing
21: and inappropriate dispensing, neither of
22: which wholesalers are authorized or
23: capable of regulating or enforcing."
24: Do you see that?

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00231

01: A. I do.
02: Q. That's a question that you
03: wanted a senator to ask the acting
04: administrator of the DEA, correct?
05: A. It was -- it was developed
06: here. Again, I don't know if it was ever
07: requested, a senator or staff or anybody.
08: Q. But at this stage it's a
09: potential question for some lawmaker to
10: ask the DEA, correct?
11: A. That's -- yes. That's the
12: context for this.
13: (Document marked for
14: identification as Exhibit
15: HDA-Kelly-23.)
16: BY MR. PIFKO:
17: Q. I'm handing you what's
18: marked Exhibit 23. If you recall,
19: earlier on in Exhibit 8, there was an
20: e-mail from Anita Ducca that attached
21: some of her draft summaries of the
22: various meetings and events that occurred
23: in connection with the industry
24: compliance guidelines and meetings with

p. 00231

00233

01: Frank law firm as well?
02: A. It does, yes.
03: Q. And who is Robert Barnett,
04: is he -- is he from Williams & Connolly
05: as well?
06: A. Yes.
07: Q. Okay. They were outside
08: counsel to HDA at this time?
09: A. Yes.
10: Q. Along with David Durkin?
11: A. That's correct.
12: Q. Okay. And so Anita Ducca is
13: there, and Scott Melville, who was your
14: predecessor was there?
15: A. Yes.
16: Q. So Ms. Ducca has a meeting
17: summary here. So it appears that Bob
18: Barnett and Rich Cooper led the
19: introductory remarks in the meeting,
20: agree?
21: A. Yes. They led off.
22: Q. Okay. So, Bob explained the
23: purpose of the meeting. He explained --
24: I'm reading from the document -- "the

p. 00233

00232

01: the DEA. And this is -- Exhibit 23, is
02: one of those attachments. She said, if
03: you recall, these were draft summaries of
04: her meetings.
05: A. Yes.
06: Q. Okay. So take a minute to
07: look at Exhibit 23, and -- which is a
08: three-page document, and let me know when
09: you're done. For the record, the Bates
10: labels are CAH_MDL2804_02489188 through
11: 190.
12: A. Okay.
13: Q. So this is a summary of the
14: first meeting that HDA had with DEA
15: concerning the industry compliance
16: guidelines, correct?
17: A. That's correct.
18: Q. It identifies that attendees
19: here from DEA and from HDMA, correct?
20: A. It does.
21: Q. And in addition to HDMA
22: members, it also identifies Richard
23: Cooper from Williams & Connolly as an
24: attendee and David Durkin from Olsson

p. 00232

00234

01: serious concerns among HDMA members
02: regarding DEA's recent actions regarding
03: suspicious orders. When HDMA first
04: contacted Williams & Connolly regarding
05: possibly challenging DEA, Bob and Rich
06: Cooper recommended an alternative that
07: was based on his prior experience with
08: other clients in similar positions."
09: Do you see that?
10: A. I do.
11: Q. Did I read that correctly?
12: A. You did.
13: Q. Do you recall that being
14: part of the discussion, that when HDMA
15: first came to Williams & Connolly to
16: potentially challenge DEA, they came up
17: with an alternative idea?
18: A. Again, I was not at HDA at
19: the time. But I understand from reading
20: this, reviewing this document, that was
21: the -- that was the initial part of the
22: discussion.
23: Q. And so Williams & Connolly
24: recommended that, instead of challenging

p. 00234

00235

01: the DEA, that the distributors develop a
02: set of business practices of their own
03: or, as this says, "a type of standard as
04: a better approach to show DEA to the
05: outside world what is intended" -- "that
06: they intend to be part of the solution
07: rather than problem"; is that correct?
08: A. That's correct. Those were
09: his words, yes.
10: Q. And that's what he told DEA
11: at this meeting?
12: A. I will take it at face value
13: that that's what was explained, yes.
14: Q. Other points that Bob
15: Barnett made were that "HDMA hoped that
16: DEA would find the guidelines acceptable
17: as a voluntary 'consent decree,' and we
18: hoped to receive some form of imprimatur
19: from you."
20: Agree?
21: A. That's what it says, yes.
22: Q. It's noted here, Bob also
23: told DEA, "These guidelines have been
24: adopted and approved by HDMA's board."

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00236

01: Agree?
02: A. Which bullet point are you
03: on?
04: Q. Second to last on the first
05: page.
06: A. Yes.
07: Q. But then it was explained
08: that HDMA and its board were open to
09: suggestions from the DEA, correct?
10: A. That's correct.
11: Q. And then it says, "If DEA
12: accepted them, you wanted to make some
13: sort of public statement about it,"
14: correct?
15: A. That's -- yes, that's what
16: it -- that's what it says, yes.
17: Q. So -- then, we're going to
18: the second page here. So it says, "After
19: Bob's introductory discussion, he turned
20: the meeting over to Richard Cooper from
21: Williams & Connolly."
22: Agree?
23: A. Yes.
24: Q. Okay. And so Rich is the

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00237

01: one who had this previous experience with
02: the FDA where they developed standards
03: that were voluntary and eventually became
04: standard practice among the medical
05: research community, and this idea of the
06: industry compliance guidelines was born
07: out of that, agree?
08: MR. WEINSTEIN: Objection to
09: form.
10: THE WITNESS: I think that's
11: what's being implied here, yes.
12: BY MR. PIFKO:
13: Q. And that's what was told to
14: DEA in connection with this meeting,
15: correct?
16: MR. WEINSTEIN: Objection to
17: form.
18: THE WITNESS: That's --
19: again, that's what it -- seems to
20: be stipulated here, yes.
21: BY MR. PIFKO:
22: Q. So a key point, according to
23: Anita's notes is that Rich Cooper from
24: Williams & Connolly made, was that "an

p. 00237

00238

01: order and question will be stopped until
02: there was an assessment and found that
03: the order was not suspicious."
04: Agree?
05: A. Where --
06: Q. Second paragraph, full
07: paragraph of Page 2.
08: A. Okay. Yes. I see that,
09: yes.
10: Q. And so then, DEA had a
11: question about "what exactly are you
12: stopping when you stop the order?"
13: A. Okay.
14: Q. And that's some discussion
15: about that.
16: Do you see that?
17: A. Yes.
18: Q. And so then, Rich Cooper
19: told DEA that "the guidelines indicated
20: that the entire order of the specific
21: product that triggered the threshold
22: should be held and not released."
23: Do you see that?
24: A. Yes.

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00239

01: Q. And then he also said, "The
02: guidelines expected that the entire order
03: for the drug product in question would be
04: held, even if part of it came under a
05: threshold."
06: Do you see that?
07: MR. WEINSTEIN: Objection to
08: form.
09: THE WITNESS: Yes. Last
10: sentence.
11: BY MR. PIFKO:
12: Q. Okay. And so that resolves
13: this partial shipment issue we discussed
14: before the break, agree?
15: MS. ROLLINS: Objection to
16: form.
17: THE WITNESS: Again, it
18: seems to indicate that there
19: was -- yes, that was going to be
20: the final recommendation in the --
21: in the guidelines.
22: BY MR. PIFKO:
23: Q. To pull the entire -- entire
24: order while the drug in question was

p. 00239

00241

01: webinars and seminars to educate the
02: members and the customers about the
03: guidelines as well"?
04: A. Yes.
05: Q. And Scott also told DEA that
06: "HDA would discuss, explain and encourage
07: acceptance of the guidelines by other
08: trade associations, including
09: manufacturing and pharmacy groups."
10: That's the second bullet
11: point on the page?
12: A. Yes, yes, yes, yes, yes.
13: Q. So you agree, a key message
14: that Scott was communicating to DEA here
15: was that HDA was going to work to make
16: sure its members and other participants
17: in the supply chain in the pharmaceutical
18: industry would implement these
19: guidelines, correct?
20: MR. WEINSTEIN: Objection to
21: form.
22: THE WITNESS: I think we --
23: we meant to basically educate the
24: rest, that they were available.

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00240

01: investigated, correct?
02: MR. WEINSTEIN: Objection to
03: form.
04: THE WITNESS: Again, I think
05: that's, yes, what this seems to
06: entail.
07: BY MR. PIFKO:
08: Q. So then the meeting was
09: handed over to Scott Melville, your --
10: your predecessor, agree?
11: A. Yes.
12: Q. And Scott told the DEA that,
13: if you look in those bullet points, that
14: "HDMA and its members intended to help
15: implement the guidelines by making
16: consultants known to them who could aid
17: in the implementation."
18: Do you see that?
19: A. I do.
20: Q. And then he said that "they
21: would discuss it with the Pain Care
22: Forum"?
23: A. Yes.
24: Q. And that "HDMA would hold

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01: Again, we are not a
02: standards agency, we are not a
03: regulatory authority. We can't
04: basically make any entity comply
05: with the guidelines. We were just
06: going to educate as many folks as
07: we could about their existence and
08: make them available.
09: BY MR. PIFKO:
10: Q. But you told DEA that you
11: wanted to help your members implement the
12: guidelines, correct?
13: MR. WEINSTEIN: Objection to
14: form.
15: THE WITNESS: That's -- yes,
16: that's what it -- that's what it
17: says here, yes.
18: BY MR. PIFKO:
19: Q. Handing you what's marked as
20: Exhibit 24.
21: (Document marked for
22: identification as Exhibit
23: HDA-Kelly-24.)
24: BY MR. PIFKO:

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00243

01: Q. It is a three-page e-mail
02: between HDA and AmerisourceBergen.
03: Bates-labeled HDA_MDL_000156499 through
04: 156501.
05: Take a minute to review
06: this, and let me know when you're done.
07: There is some discussion
08: about whether Chris Zimmerman from
09: AmerisourceBergen is going to serve as
10: a -- a chairman of a committee. I'm not
11: interested in that part of the discussion
12: here.
13: A. Okay.
14: Q. This goes back to earlier in
15: the process of developing the industry
16: compliance guidelines or best practices,
17: agree, it's back in early January 2008?
18: A. Yes.
19: Q. And this is before this
20: meeting with DEA, correct?
21: A. It is.
22: Q. Okay. And in this e-mail on
23: the first page, 156499, Mr. Zimmerman
24: tells HDA's Anita Ducca, "I think we need

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01: already under strict adherence to
02: a specific plan with -- directly
03: with the DEA that satisfies their
04: obligations. But it's specific to
05: those companies individually,
06: therefore, a model plan or
07: guidelines is irrelevant for them.
08: BY MR. PIFKO:
09: Q. And they have no plan on
10: implementing them at this time, correct?
11: MS. ROLLINS: Objection to
12: form.
13: MR. WEINSTEIN: Objection to
14: foundation and form.
15: THE WITNESS: Because they
16: have their own policies in place.
17: BY MR. PIFKO:
18: Q. You said here that they have
19: a plan that satisfies the DEA. Where
20: does it say that it satisfies the DEA?
21: A. I'm deducing from this
22: document that since ABC has an agreement
23: with DEA, it does not matter what best
24: practices HDMA develops because ABC must

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01: to discuss the suspicious order project.
02: Since ABC has an agreement with DEA, it
03: does not matter what best practices HDMA
04: develops because ABC must adhere to its
05: written agreement with DEA. I assume
06: Cardinal will be in the same boat.
07: Therefore, I'm not sure what benefit ABC
08: would receive from this project."
09: Do you see that?
10: A. I do.
11: Q. Did I read that correctly?
12: A. You do.
13: Q. Okay. So you agree that at
14: this time Mr. Zimmerman is saying that
15: he's not going to implement any
16: guidelines or best practices, and he
17: assumes Cardinal is not going to either,
18: correct?
19: MS. ROLLINS: Object to
20: form.
21: MR. WEINSTEIN: Objection to
22: form. Foundation.
23: THE WITNESS: I think what
24: he's implying is that they are

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00246

01: adhere to its written agreement with DEA.
02: Q. What about Cardinal?
03: MR. WEINSTEIN: Objection to
04: form.
05: MS. CHARLES: Objection to
06: form.
07: BY MR. PIFKO:
08: Q. It doesn't say anything like
09: that about Cardinal, does it?
10: MR. WEINSTEIN: Objection to
11: form. Foundation.
12: THE WITNESS: An individual
13: from ABC insinuates that Cardinal
14: may be a similar position due to
15: a -- maybe a consent decree that
16: Cardinal entered into with DEA as
17: well that would be in the same
18: constriction with regard to their
19: practices that ABC is at the time.
20: BY MR. PIFKO:
21: Q. And so the HDA knew this
22: information before it had the meeting
23: with DEA, correct?
24: A. Obviously we were apprised

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00247

01: that they were basically not going to be
02: of help in developing the guidelines or
03: adopting the guidelines, because they are
04: there are under a separate agreement.
05: Q. Do you know if
06: AmerisourceBergen ever asked DEA if it
07: could follow the guidelines as an
08: improvement on measures it was already
09: engaged in?
10: MS. ROLLINS: Objection to
11: form.
12: MR. WEINSTEIN: Objection to
13: form. Foundation.
14: THE WITNESS: I do not.
15: BY MR. PIFKO:
16: Q. No one ever told you that
17: they had requested anything from DEA as
18: far as being able to implement the
19: industry compliance guidelines?
20: MS. ROLLINS: Objection to
21: form.
22: THE WITNESS: That ABC had
23: requested? Again, I don't know.
24:

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01: applicable to various size
02: companies and be able to adapt.
03: So again I don't know if
04: anybody adopted the entire
05: document verbatim or not. And we
06: didn't ask.
07: BY MR. PIFKO:
08: Q. You don't know if anybody
09: adopted parts of the document either,
10: correct?
11: MR. WEINSTEIN: Objection to
12: form.
13: THE WITNESS: We don't.
14: BY MR. PIFKO:
15: Q. So sitting here today, you
16: don't know, and at no time does HDMA know
17: if any members or other distributors
18: adopted all or part of the industry
19: compliance guidelines, correct?
20: MR. WEINSTEIN: Objection to
21: form.
22: THE WITNESS: I don't know,
23: nor did we ask. And again, I
24: stated before, we are not a

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00248

01: BY MR. PIFKO:
02: Q. Same question about Cardinal
03: Health.
04: MS. CHARLES: Objection to
05: form.
06: THE WITNESS: Again I don't
07: know. I don't know.
08: BY MR. PIFKO:
09: Q. To your knowledge, did any
10: distributor implement the industry
11: compliance guidelines?
12: MR. WEINSTEIN: Objection to
13: form. Foundation.
14: THE WITNESS: Again, I don't
15: know. They were -- they were
16: guidelines. Many of the
17: companies, from what I understand,
18: already had various processes in
19: place. These guidelines were
20: developed to better inform them
21: about expectations within the DEA.
22: And if they -- they could beg and
23: borrow, and again it was meant to
24: be kind of something that could be

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00250

01: regulatory authority; we are not a
02: standard-setting body. We are
03: simply doing our best to inform
04: our members about existing
05: policies.
06: BY MR. PIFKO:
07: Q. And to your knowledge, no
08: pharmaceutical manufacturer ever adopted
09: the industry compliance guidelines or any
10: portion of them, correct?
11: MR. WEINSTEIN: Objection to
12: form.
13: MS. MACKAY: And foundation.
14: THE WITNESS: And again,
15: they were not -- they were not
16: developed for manufacturers. They
17: were developed for our core
18: members, the distributor members
19: of HDA.
20: BY MR. PIFKO:
21: Q. But you did discuss them
22: with the Pain Care Forum, which included
23: manufacturers, correct?
24: MR. WEINSTEIN: Objection to

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00251

01: form.

02: THE WITNESS: Among many

03: other groups, yes. A lot of

04: pharmacies groups, everybody in

05: the supply chain.

06: BY MR. PIFKO:

07: Q. Okay. And just to be

08: clear -- I think you had the answer, but

09: I don't think we have a clear record.

10: To your knowledge, no

11: distributor, manufacturer, or pharmacy

12: has ever implemented the guidelines or

13: any portion of the guidelines, correct?

14: MR. WEINSTEIN: Objection to

15: form. Foundation.

16: THE WITNESS: Again, I think

17: every distributor member has their

18: own compliance guidelines that are

19: basically developed and put in

20: place for their company, their

21: specific customer base, et cetera.

22: I don't know that anybody kind of

23: copied the industry compliance

24: guidelines and made it part of

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00253

01: ICG --

02: MR. WEINSTEIN: Objection to

03: form.

04: BY MR. PIFKO:

05: Q. -- in February 25th, 2011?

06: MR. WEINSTEIN: Objection to

07: form.

08: THE WITNESS: No. I think

09: what we asked was, were the ICGs

10: still relevant. That was -- we

11: wanted to make sure that our

12: guidelines were still

13: relatively -- we weren't asking

14: whether they were consistent with

15: our -- with basically our

16: guidance. Were our guidelines

17: still relevant and consistent four

18: years of their publication or

19: three years after the publication.

20: BY MR. PIFKO:

21: Q. Well, no, it says -- it

22: literally says in the document, "Request

23: review of consistency between the ICG and

24: member practices."

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00252

01: their own protocols and

02: procedures. I don't know. Nor

03: did we ask.

04: BY MR. PIFKO:

05: Q. I want to turn your

06: attention back to Exhibit 2. Are you

07: there?

08: A. Yes. I'm at Exhibit 2.

09: Q. You want you to go to the

10: page Bates-labeled HDA_MDL_000081366.

11: It's got dates that start with

12: September 30, 2010, to March 2011.

13: Do you see that?

14: A. Yes.

15: Q. So on February 25, 2011, it

16: says, "ExComm concurs with government

17: policy" -- government public policy

18: council directive. Requests review of

19: consistency between the ICG and member

20: practices."

21: Do you see that?

22: A. Yes.

23: Q. So HDA did review the

24: consistency of member practices with the

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00254

01: A. Is the ICG current.

02: Q. Right. But there's a -- you

03: were reviewing whether there was

04: consistency between the member practices

05: and the ICG, correct?

06: MR. WEINSTEIN: Are you

07: testifying for the witness or is

08: there a question in there?

09: MR. PIFKO: I'm asking him a

10: question.

11: THE WITNESS: Again -- and,

12: again, this is just as a statement

13: in a -- in a chronology here. I

14: think the -- the request was to

15: basically look at the ICGs and

16: determine based on what they are

17: doing and what's confronting them

18: in that marketplace, at that time,

19: three years after the publication,

20: are they still relevant and are

21: they still current.

22: BY MR. PIFKO:

23: Q. Right. But there's a

24: comparison of the ICGs and the member

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00255

01: practices at that time, correct?
02: MR. WEINSTEIN: Objection to
03: form.
04: THE WITNESS: That we
05: requested the individual member
06: companies to look at our ICGs and
07: compare them with their practices,
08: and let us know if they were still
09: relevant.
10: We did not review individual
11: company member practices. And nor
12: could we with our antitrust.
13: BY MR. PIFKO:
14: Q. Well, you did. You
15: requested the -- the member companies'
16: practices when you developed the industry
17: compliance guidelines. You've already
18: testified to that, it's all over the
19: documents.
20: A. We -- we submitted -- we
21: submitted a questionnaire. We asked them
22: to respond to the questionnaire based on
23: what their practices were. And again we
24: didn't -- we didn't ask for their

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01: comfortable responding to the
02: questionnaire, did.
03: We did not ask for their
04: policies. We asked them to
05: respond to the questionnaire. To
06: some extent, it --
07: BY MR. PIFKO:
08: Q. That's -- that's not --
09: that's not what the document says. And
10: that's not what you testified to earlier.
11: MR. WEINSTEIN: Objection to
12: form. Wait for a question.
13: BY MR. PIFKO:
14: Q. Remember, that we are under
15: oath here?
16: A. I do.
17: MR. WEINSTEIN: Sir, come
18: on, Mark, give me a break.
19: MR. PIFKO: He's trying to
20: change his testimony.
21: MR. WEINSTEIN: Give me a
22: break, Mark. Ask your questions.
23: BY MR. PIFKO:
24: Q. Exhibit 10 talks about the

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00256

01: practices verbatim.
02: Q. You did --
03: A. To the extent that they were
04: comfortable --
05: Q. Ms. Ducca expressly said she
06: would facilitate that with the
07: consultant. Are you now --
08: MR. WEINSTEIN: Objection to
09: form.
10: BY MR. PIFKO:
11: Q. -- disputing what you said
12: on the record before?
13: MR. WEINSTEIN: Objection to
14: form.
15: THE WITNESS: No. That --
16: MR. WEINSTEIN:
17: Mischaracterizes testimony.
18: THE WITNESS: I'm not --
19: I'm -- I'm not disputing that at
20: all.
21: The consultant was brought
22: in, developed a questionnaire.
23: The questionnaire was submitted to
24: the membership. Those that felt

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00258

01: processes that the consultant's going to
02: use, and it says, "Obtaining where
03: available copies of HDMA member
04: companies' internal suspicious order
05: business practices." And Anita Ducca
06: said she was going to handle that.
07: And then in Exhibit 12, she
08: says, "We've been contacting our members
09: to request their suspicious order
10: information. This is the first of a few
11: e-mails I'll be sending you." She sends
12: the policies from Henry Schein. It's
13: separate than the -- the interview
14: questionnaire that was discussed.
15: MR. WEINSTEIN: Just wait
16: for the question.
17: BY MR. PIFKO:
18: Q. So are you disputing that
19: HDA requested copies of its members'
20: suspicious order practices?
21: MR. WEINSTEIN: Objection to
22: form.
23: THE WITNESS: I'm not -- I'm
24: not disputing what was -- what was

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00259
01: typed. I'm not aware that we were
02: receiving verbatim copies of their
03: suspicious order monitoring
04: protocols.
05: BY MR. PIFKO:
06: Q. That was expressly part of
07: the protocol.
08: MR. WEINSTEIN: Objection to
09: form.
10: BY MR. PIFKO:
11: Q. Are you disputing that?
12: MR. WEINSTEIN: Objection to
13: form.
14: THE WITNESS: Again, are you
15: referencing a specific --
16: BY MR. PIFKO:
17: Q. Yeah. Exhibit 10 --
18: A. Exhibit 10.
19: Q. It says she is going to
20: review the members' suspicious order
21: policies.
22: A. This is in the -- where are
23: you referring to?
24: Q. Page 2.

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00261
01: stuff from Henry Schein and says she is
02: sending others. So --
03: MR. WEINSTEIN: Objection to
04: form.
05: BY MR. PIFKO:
06: Q. -- are you disputing that
07: HDA collected suspicious order practices
08: from its members?
09: MR. WEINSTEIN: Objection to
10: form.
11: THE WITNESS: I'm not
12: disputing that.
13: BY MR. PIFKO:
14: Q. Okay. That's all I'm
15: asking.
16: A. Again, I don't know what
17: attachments were submitted by Henry
18: Schein.
19: Q. I'm handing you what's
20: marked as Exhibit 25.
21: (Document marked for
22: identification as Exhibit
23: HDA-Kelly-25.)
24: BY MR. PIFKO:

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00260
01: MR. WEINSTEIN: Of
02: Exhibit 10.
03: MR. PIFKO: 3(B).
04: THE WITNESS: Where
05: available copies of HDMA member
06: copies --
07: BY MR. PIFKO:
08: Q. "Obtaining where available
09: copies of HDMA member companies' internal
10: suspicious business order practices."
11: Then if you look at Page 3
12: she says, "Contacting HDMA members to, A,
13: request copies of their current
14: suspicious orders business practices.
15: HDMA can facilitate this by sending an
16: e-mail to our members making the
17: request."
18: That's different from the
19: interviews. C is the interviews.
20: MR. WEINSTEIN: Objection to
21: form.
22: THE WITNESS: Again --
23: BY MR. PIFKO:
24: Q. In Exhibit 12 she sends Bill

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00262
01: Q. Exhibit 25 is a document
02: Bates-labeled HDA_MDL_000213079 through
03: 213088. It's a document, PowerPoint
04: presentation entitled, "DEA Suspicious
05: Orders: Recommended Industry Compliance
06: Guidelines. Regional round table. May
07: 7, 2008."
08: Take a minute to review
09: this, and let me know when you're done.
10: A. Okay.
11: Q. Do you know who this
12: presentation was made to?
13: A. From what I understand, this
14: was before I joined the organization.
15: There were a series of briefings that we
16: would provide to members that weren't
17: able to travel that much. Smaller
18: companies that were in different parts of
19: the country.
20: So we would have regional
21: round tables where the smaller companies
22: would be able to get to a central
23: location and we'd come in and update them
24: on key issues.

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Page 70

00263

01: Q. Okay. So this is an example
02: of updating some of these smaller
03: companies about the industry compliance
04: guidelines and the process that was
05: engaged to develop them and roll them
06: out?
07: A. That seems to be, yes, what
08: it was.
09: Q. It's got some summary of DEA
10: reaction on Page 213085 which is
11: consistent with the notes that Ms. Ducca
12: took of the first meeting. Agree?
13: MS. CHARLES: Object to
14: form.
15: THE WITNESS: Yes.
16: (Document marked for
17: identification as Exhibit
18: HDA-Kelly-26.)
19: BY MR. PIFKO:
20: Q. I'm handing you what's
21: marked as Exhibit 26. These are
22: Ms. Ducca's notes from the second meeting
23: with DEA on suspicious orders which was
24: attached to Exhibit 8, I believe.

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00265

01: form.
02: THE WITNESS: Yes.
03: BY MR. PIFKO:
04: Q. And it's got the attendees
05: here from DEA, it includes Linden Barber,
06: Cathy Gallagher, Robert Gleason, agree?
07: A. Yes.
08: Q. And then from HDMA, we've
09: got Ms. Ducca, Scott Melville. And
10: you've got outside counsel, Robert
11: Burnett, Richard Cooper, and David
12: Durkin, agree?
13: A. Yes.
14: Q. Okay. So they just go
15: through the draft guidelines that were
16: provided to them, which are the ones that
17: were in Exhibit 21.
18: So then, it goes through
19: page by page providing thoughts and
20: comments DEA has, agree?
21: A. Yes, that's what these notes
22: do.
23: Q. That's what's reflected in
24: Exhibit 26, correct?

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00264

01: For the record, it's
02: Bates-labeled CAH_MDL2804_02489191
03: through 196. Take a minute to review
04: this, and let me know when you're done.
05: A. Okay.
06: Q. Are you done? You reviewed
07: this?
08: A. I reviewed it, yes.
09: Q. So these are Ms. Ducca's
10: notes of the second meeting with DEA,
11: correct?
12: A. Yes.
13: Q. And if you recall, from the
14: notes from the first meeting, one of the
15: comments was that they welcomed DEA's
16: input on the draft that had been shared
17: at the prior meeting, agree?
18: A. Yes.
19: Q. And so then, this is DEA
20: providing its comments on the industry
21: compliance guidelines that had been
22: provided to them at the prior meeting,
23: agree?
24: MR. WEINSTEIN: Objection to

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00266

01: A. Yes.
02: Q. Okay. So one comment DEA
03: has is that, "It's recommended that you
04: add into the outline that once an order
05: is determined to be suspicious, it
06: shouldn't be shipped. DEA understood
07: that it was in the body of the
08: guidelines, but they wanted to see it
09: upfront in the outline as well." Agreed?
10: MR. WEINSTEIN: Objection to
11: form.
12: THE WITNESS: I'm sorry,
13: where -- where --
14: BY MR. PIFKO:
15: Q. Page 3.
16: A. Page 3, I'm sorry.
17: Q. No I'm on the first page of
18: Exhibit 26. But I'm looking at the
19: comment from Page 3.
20: A. Oh, I'm sorry. Okay, yes.
21: Q. DEA is just emphasizing that
22: the -- if an order is suspicious, it
23: shouldn't be shipped. They want that up
24: in the front in the outline, even though

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00267

01: it's in the body of the document, agreed?
02: A. That's what this notes says,
03: yes.
04: Q. The comment for Page 4, Item
05: 1B is saying that for a questionnaire
06: that might be to a distributor's
07: customer, DEA wants the industry to be
08: aware that even if you obtain a signed
09: document, that's not going to be a
10: defense; distributors have to do more to
11: identify the legitimacy, agree?
12: MR. WEINSTEIN: Objection to
13: form.

14: THE WITNESS: Yes, that's
15: what it says.

16: BY MR. PIFKO:

17: Q. Turning to the second page.
18: It says, a comment halfway down the page
19: on Page -- the comment for Page 6.
20: There's actually two. I'm looking at
21: the -- oh, there's actually three. I'm
22: looking at the second one. It says,
23: "Several times they" -- which is DEA,
24: "they said that the procedures" --

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00269

01: Q. "They also want the initial
02: screen of orders to focus on A, patterns
03: of ordering, comparing the present order
04: to, one, past orders from the same
05: customer including whether the frequency
06: of orders is suspicious; two, orders from
07: similar customers; and, three, orders
08: from other establishments of the same
09: type in the locale or region." Agree?
10: A. That's what it says.
11: Q. Okay. And then they also
12: want the initial screens of orders to
13: focus on combination of controlled
14: substances ordered, agree?
15: A. That's what it says, yes.
16: Q. Then going to the third
17: page, at the top, another comment that
18: DEA made here, it says, was that the term
19: "order of interest" did not have legal
20: standing.
21: Do you see that?
22: A. I do.
23: Q. Okay. And that was
24: something that DEA conveyed at this

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00268

01: "procedures used by members should be
02: robust and adaptable," agree?
03: MR. WEINSTEIN: Objection to
04: form.
05: THE WITNESS: That's what it
06: says.
07: BY MR. PIFKO:
08: Q. Okay. And then the longer
09: comment here for Section 2, monitoring on
10: suspicious orders, the second paragraph
11: here, it says, "DEA seemed to think that
12: thresholds focus primarily on volumes and
13: they expressed the view that an exclusive
14: or even principal focus on volumes is
15: inadequate."
16: Do you see that?
17: A. I do.
18: Q. Do you agree that that's
19: what DEA told HDMA during this meeting?
20: A. I have no reason to doubt
21: what's written here.
22: Q. Okay. And that's what's
23: written here, correct?
24: A. That's what's written here.

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00270

01: meeting, correct?
02: A. Again, I'll take it from
03: this, yes, that they did that.
04: Q. And then it says, "DEA
05: emphasized that orders should not remain
06: in the orders of interest category for
07: lengthy periods."
08: Do you see that?
09: A. Yes.
10: Q. "They should be investigated
11: expeditiously and promptly resolved as
12: either suspicious or not suspicious."
13: Agree?
14: MR. WEINSTEIN: Objection to
15: form.
16: THE WITNESS: That's what it
17: says, yes.
18: BY MR. PIFKO:
19: Q. Okay. Then there's some
20: comments about the language about
21: thresholds that was in the draft industry
22: compliance guidelines.
23: Do you see that section?
24: A. I do.

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00271

01: Q. Okay. So the first is that,
02: "DEA thought it might be interpreted to
03: mean excessive volumes only. And then
04: HDMA responded that their intent was to
05: be broader and to include frequency as a
06: factor."
07: Do you see that?
08: A. I do.
09: Q. Okay. "DEA asked HDA to
10: expand the explanation of thresholds,"
11: agreed?
12: A. That's what it says, yes.
13: Q. And then, "DEA asked that
14: the industry compliance guidelines say
15: the drug or drugs that cause an order to
16: be an order of interest should not be
17: shipped where the order is an order of
18: interest."
19: Do you see that?
20: A. I do.
21: Q. Okay. You agree that that
22: was something that the DEA conveyed at
23: this meeting?
24: A. Again, I have no reason to

p. 00271

00273

01: Q. Going to Page 4. There is
02: some discussion about how to evaluate
03: orders that aren't just of high volume.
04: It says, "They gave the example of an
05: internet pharmacy that might be ordering
06: from multiple distributors and that might
07: not order enough to go over a threshold
08: over a period of time, but could be
09: identified by a pattern of how and when
10: they ordered.
11: "For example, they thought
12: if a pharmacy ordered only every three to
13: four months, but then when they did so,
14: ordered a large volume, that might be a
15: signal the pharmacy was doing business
16: with several distributors and rotating
17: which one they ordered from?"
18: Do you see that?
19: A. I do.
20: Q. That was something that was
21: communicated?
22: A. It's written here. I have
23: no reason to doubt that that was what was
24: stated.

p. 00273

00272

01: doubt what was stated here on this paper.
02: Q. And then finally, it says,
03: "DEA suggested that we delete the second
04: paragraph under C, develop thresholds to
05: identify orders of interest."
06: Do you see that?
07: A. I do.
08: Q. It says, "DEA has backed
09: away from the standard of three times the
10: monthly overage order for Schedule II and
11: ARCOS-reportable Schedule III products.
12: DEA suggested that we substitute a
13: paragraph based on more recent DEA
14: guidance."
15: Do you see that?
16: A. I do.
17: Q. So you understood that DEA
18: was communicating here not to use the
19: three times multiplier, correct?
20: MR. WEINSTEIN: Objection to
21: form. Foundation.
22: THE WITNESS: That seems to
23: be what this indicates, yes.
24: BY MR. PIFKO:

p. 00272

00274

01: Q. Okay. And then we go to the
02: section on Page 8 in the guidelines,
03: "Stop shipments of an order of interest."
04: Do you see that?
05: A. I do.
06: Q. And then it says, "DEA asked
07: us to reemphasize that an order should
08: not be shipped" -- and it's underlined --
09: "if there was reason to believe there was
10: a problem."
11: Do you see that?
12: A. I do.
13: Q. So DEA made that point
14: again, correct?
15: A. Yes.
16: MR. WEINSTEIN: Objection to
17: form.
18: BY MR. PIFKO:
19: Q. And then it says, "In fact,
20: they asked us to add in that if one
21: controlled substance in the order could
22: be a problem, then other controlled
23: substances in the order may also be a
24: problem and the distributor should

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00275

01: consider holding the others."
02: Do you see that?
03: A. I do.
04: Q. Did I read that correctly?
05: A. You did.
06: Q. It's your understanding that
07: DEA communicated this to HDA in providing
08: comments on the guidelines, correct?
09: A. I have no reason to doubt
10: what's written here.
11: Q. They gave an example of an
12: order where the volume of hydrocodone
13: triggered a threshold, but that both
14: hydrocodone and alprazolam were included
15: in the same order.
16: Do you see that?
17: A. I do.
18: Q. And then it says, at the
19: bottom of that paragraph, "If one part
20: was suspicious, wouldn't all of it be
21: suspicious?"
22: Do you see that?
23: A. I do.
24: Q. Do you agree that that was

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00277

01: read the full paragraph.
02: BY MR. PIFKO:
03: Q. Do you see where I was
04: reading?
05: A. I did -- I did see where you
06: were reading, yes.
07: Q. Okay. You understood that
08: DEA communicated that during this
09: meeting?
10: A. Again, I have no reason to
11: doubt what's written here.
12: Q. I want to go to the last
13: page of this document. The comment from
14: Page 11, "DEA asked us to emphasize that
15: suspicious order must be reported to DEA
16: whether the wholesaler ships or not, and
17: to emphasize that timeliness of notice is
18: very important."
19: Do you see that?
20: A. I do.
21: Q. Do you agree that that was
22: something communicated during this
23: meeting?
24: A. I do.

p. 00277

00276

01: something communicated at this meeting?
02: MS. CHARLES: Object to
03: form.
04: MR. WEINSTEIN: Objection to
05: form.
06: THE WITNESS: Again, that's
07: written clearly here that that's
08: what they said.
09: BY MR. PIFKO:
10: Q. Then at the last page --
11: part in that section it says, "DEA's
12: point was that in some circumstances, the
13: connection between that drug and another
14: drug in the order should lead the
15: wholesaler not to ship the other drug as
16: well. Again, in their view, looking at
17: volume ordered drug by drug is not
18: enough, and basing thresholds solely on
19: volume is not enough. Even if an order
20: for a drug that does not meet a volume
21: threshold may be suspicious in light of
22: other aspects of the order."
23: Do you see that?
24: MR. WEINSTEIN: You didn't

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00278

01: Q. Then there's some -- a
02: section, "Additional Recommendations."
03: "DEA asked us to further" --
04: "to either expand this bullet or create a
05: new bullet to highlight the distributor's
06: own experience may indicate a need to
07: revise their system for suspicious order
08: monitoring."
09: Do you see that?
10: A. I do.
11: Q. So you understood that DEA
12: was saying, based on a distributor's own
13: experience, they might need to make
14: changes or improvements to their system
15: over time?
16: MR. WEINSTEIN: Objection to
17: form.
18: BY MR. PIFKO:
19: Q. Correct?
20: MR. WEINSTEIN: Same
21: objection.
22: THE WITNESS: That seems to
23: indicate what -- yes, what was
24: said.

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00279

01: BY MR. PIFKO:

02: Q. And then there's additional
03: comments that DEA raised that are
04: provided in bullet points here at the
05: end. Agree?
06: A. I see them.
07: Q. Five of them?
08: A. Yes.
09: Q. One is yet another comment
10: that if an order is -- there's concerns
11: or questions, it shouldn't be shipped,
12: agree?

13: MR. WEINSTEIN: Objection to
14: form.

15: THE WITNESS: The first
16: bullet point?

17: BY MR. PIFKO:

18: Q. Yeah. That's what it says?
19: A. That's what it says.
20: Q. They want reports on all
21: orders, even if it's not shipped?
22: A. On all suspicious orders.
23: Yes. Bullet Point 2.
24: Q. Again, a comment about

p. 00279

00281

01: procedures, these would -- these would
02: have been shared with other members as
03: well, correct?

04: MR. WEINSTEIN: Objection to
05: form.

06: MS. WICHT: Objection to
07: form.

08: THE WITNESS: Again, I can't

09: say for certain. This is labeled
10: as a draft. I'm not sure if it
11: was sent to the RAC or another
12: group, until -- again, all I have
13: is the form in front of me so...
14: I would -- I would imagine
15: so, that usually we sent -- we're
16: usually in the habit of
17: summarizing those meetings and
18: sending them out to the regulatory
19: affairs committee.

20: BY MR. PIFKO:

21: Q. And as we looked at in one
22: of the other documents, the outcome of
23: these meetings was critical to forming
24: HDA's future strategies, correct?

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00280

01: timeliness in Bullet 3, agree?
02: A. Yes.
03: Q. And then 4, it says, "DEA
04: wants reports of suspicious orders even
05: if there is some question about the
06: dispenser status as a customer. For
07: example, if during a background check of
08: a potential customer, the customer
09: indicates that they might be placing
10: orders that could be suspicious, DEA
11: wants to know, even if the pharmacy in
12: question does not become a customer."
13: Agree, that's what it says?
14: A. That's what it says, yes.
15: Q. So you understood that DEA
16: communicated that as well during this
17: meeting?
18: A. Again, I have no reason to
19: doubt what's written here.
20: Q. Okay. We know these
21: comments were shared with Cardinal,
22: because we have the e-mail.
23: To your knowledge, in the
24: ordinary course of HDA's processes and

p. 00280

00282

01: MR. WEINSTEIN: Objection to
02: form.

03: THE WITNESS: It was -- I
04: mean feedback from the DEA was an
05: important component to finalizing
06: and -- and fine-tuning the ICGs,
07: yes.

08: BY MR. PIFKO:

09: Q. And developing other
10: strategies. Remember we looked at that
11: discussion of strategy for the Hill. It
12: said that the meetings under industry
13: compliance guidelines were going to be
14: key to formulating additional strategies,
15: agreed?

16: A. Yes.

17: Q. Okay. So HDA certainly
18: would have shared the views of DEA to its
19: members after this meeting, agree?

20: MR. WEINSTEIN: Objection to
21: form.

22: THE WITNESS: Again, I don't
23: doubt that they did. I just --
24: I'm looking at a draft document.

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00283

01: So again, I don't doubt that
02: this was finalized and the edits
03: made here were incorporated and a
04: final document was submitted to
05: the regulatory affairs committee.
06: BY MR. PIFKO:
07: Q. And you agree that the
08: members of the regulatory affairs
09: committee would have been interested to
10: know how this DEA meeting turned out,
11: correct?
12: MR. WEINSTEIN: Objection to
13: form.
14: MS. CHARLES: Objection.
15: Form.
16: MS. MACKAY: Objection.
17: MS. ROLLINS: Foundation.
18: MS. WICHT: Objection to
19: form.
20: MR. WEINSTEIN: Foundation.
21: THE WITNESS: I think -- I
22: think they would be interested,
23: yes.
24: BY MR. PIFKO:

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00284

01: Q. I'm handing you what's
02: marked as Exhibit 27.
03: (Document marked for
04: identification as Exhibit
05: HDA-Kelly-27.)
06: BY MR. PIFKO:
07: Q. You don't need to read this
08: thing in its entirety. But this is the
09: final guidelines, correct? You can take
10: a minute to review it. That's all I want
11: to ask you.
12: For the record, Exhibit 27
13: is a document Bates-labeled
14: HDA_MDL_00218651 through 218665.
15: A. Yes, I would agree that this
16: is the final version of the industry
17: compliance guidelines.
18: (Document marked for
19: identification as Exhibit
20: HDA-Kelly-28.)
21: BY MR. PIFKO:
22: Q. I'm handing you what's
23: marked Exhibit 28, single-page document,
24: a letter from the DEA dated October 17,

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00285

01: 2008, Bates-labeled CAH_MDL2804_02489203.
02: Take a minute to review this. This is a
03: letter HDA received after finalizing the
04: guidelines from DEA, correct?
05: A. I'm sorry. Could you
06: restate it?
07: Q. Take a minute to review it.
08: And let me know when you're done.
09: A. All right.
10: Q. Okay. This is a letter that
11: DEA receive -- or sorry, DEA sent to HDA
12: after the guidelines were completed,
13: correct?
14: A. That's my understanding,
15: yes.
16: Q. This is to HDA's president,
17: John Gray?
18: A. Yes.
19: Q. Okay. It says in the first
20: paragraph, second sentence, "The elements
21: set forth in the industry compliance
22: guidelines reporting suspicious orders
23: and preventing diversion of controlled
24: substances are important to sustaining

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00286

01: effective controls to guard against
02: diversion of controlled substances."
03: You agree that's what it
04: says?
05: A. That's what it says, yes.
06: Q. Second paragraph, last
07: sentence, "All distributors must
08: implement processes and procedures to
09: effectively ensure that controlled
10: substances are not diverted to illicit
11: use."
12: Do you agree with me that's
13: what it says?
14: A. Yes.
15: Q. Third paragraph, first
16: sentence, "Although diversion control is
17: not a one-size-fits-all effort, companies
18: that implement processes and procedures
19: that effectively accomplish these
20: objectives will do much to ensure that
21: vital controlled substances are not
22: diverted to illegitimate uses."
23: Agree that's what it says?
24: A. Yes.

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00287

01: Q. When HDA received this, did
02: it send this letter to its members?
03: MS. MACKAY: Objection to
04: form.
05: THE WITNESS: I imagine it
06: did. This is the type of
07: correspondence that we would make
08: available to the members.
09: MR. PIFKO: We'll take a
10: break after this document.
11: (Document marked for
12: identification as Exhibit
13: HDA-Kelly-29.)
14: BY MR. PIFKO:
15: Q. Handing you what's been
16: marked as Exhibit 29. For the record,
17: Exhibit 29 is a webinar slide
18: presentation dated Friday, November 14th,
19: 2008. The title "Industry Compliance
20: Guidelines. Reporting Suspicious Orders
21: and Preventing Diversion of Controlled
22: Substances." It's Bates-labeled
23: HDA_MDL_000145918 through 145968.
24: Take a minute to review it.

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00289

01: its members?
02: MR. CRAWFORD: Objection to
03: form.
04: THE WITNESS: Its -- yeah,
05: its core members. Its distributor
06: members --
07: BY MR. PIFKO:
08: Q. Okay.
09: A. -- on technical issues.
10: Q. So it's HDA's practice to
11: provide webinars to core distributor
12: members, correct?
13: A. Yes.
14: Q. And this is a webinar dated
15: Friday, February (sic) 14, 2008, agreed?
16: A. Yes.
17: Q. About a month after you got
18: the letter from DEA, Exhibit 28, agree?
19: A. Yes.
20: Q. It's got two presentations,
21: one from Ms. Ducca, and one from David
22: Durkin, agree?
23: A. Yes.
24: Q. So it's got some background

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00288

01: I only have a couple of questions about a
02: couple of the slides.
03: A. Okay.
04: Q. So you recall in the first
05: meeting with DEA about the industry
06: compliance guidelines on April 15, 2008,
07: one of the thing HDA told DEA that it was
08: going to engage in an educational
09: outreach concerning the guidelines,
10: correct?
11: A. Correct.
12: Q. Okay. Do you understand
13: that to be a part of the educational
14: outreach?
15: A. I do, yes.
16: Q. Do you know who this was
17: given to?
18: A. I do not know. I have no
19: idea who the participants were.
20: Q. This is a webinar. Is it
21: common practice for HDA to provide
22: webinars?
23: A. Yes.
24: Q. And it provides webinars to

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00290

01: about how the guidelines were developed
02: and why they were developed. If you look
03: at Slide 8, there's a section,
04: history/background.
05: A. Yes.
06: Q. Okay. One of the points of
07: history and background that's provided on
08: Slide 8 is that intensity stepped up, and
09: the DEA sent those three Rannazzisi "Dear
10: Registrant" letters and suspended
11: distributors' registration, agree?
12: A. Yes.
13: Q. And that was part of what
14: led to the development of these industry
15: compliance guidelines, correct?
16: A. Yes.
17: Q. Then there is -- then next
18: slide, Slide 9 is, what is driving the
19: DEA. So why -- why is that happening,
20: agree? Why are we getting these "Dear
21: Registrant" letters and suspension of
22: registrations?
23: MR. WEINSTEIN: Objection to
24: form.

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00291

01: THE WITNESS: These are,
02: yeah, several criteria that were
03: listed, yes.
04: BY MR. PIFKO:
05: Q. Okay. It says prescription
06: drug abuse. And it talks about increase
07: in prescribing for pain, nonmedical
08: prescription drug use is up 80 percent
09: from 2000. Am I reading that correct?
10: A. That's what -- yes.
11: Q. And there is some discussion
12: about the "Dear Registrant" Rannazzisi
13: letters. Some of this we've seen in the
14: other presentations, agree? Such as the
15: October 31, 2008, one? Or I'm sorry,
16: January 31, 2008, one?
17: MR. WEINSTEIN: Objection to
18: form.
19: THE WITNESS: Yes.
20: BY MR. PIFKO:
21: Q. Then you go to Slide 15. It
22: tells you the purpose of the industry
23: compliance guidelines and the DEA
24: communications, agree?

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00292

01: MR. WEINSTEIN: Objection to
02: form.
03: THE WITNESS: Yes.
04: BY MR. PIFKO:
05: Q. So, the purpose -- one of
06: the purposes is to head off further
07: enforcement of regulatory action, agree?
08: A. That's what it states.
09: Q. One of them is to
10: demonstrate our members' commitment.
11: Do you see that?
12: A. Yes.
13: Q. Another one says to see
14: distributors as part of the solution.
15: Do you see that?
16: A. Yes.
17: Q. If you go to Slide 24. Some
18: additional advice on what's a suspicious
19: order from DEA, agreed?
20: A. It says, "Anecdotal advice
21: from DEA," yes.
22: Q. And it's got seven bullet
23: points about criteria that can make an
24: order suspicious, agree?

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00293

01: A. Yes there are certain bullet
02: points, yes.
03: Q. If you go to Page 29, it's
04: got a timeline and set of events of
05: background about the industry compliance
06: guidelines development.
07: Do you see that?
08: A. I'm sorry.
09: Q. 29?
10: A. Yes.
11: Q. Are you there?
12: A. I'm on Slide 29, yes.
13: Q. So it says, "The regulatory
14: affairs committee" -- that's the
15: committee that developed them, correct?
16: A. Yes.
17: Q. And then they were reviewed
18: by counsel, yes?
19: A. That's correct.
20: Q. And then outreach to related
21: interest groups. That includes the Pain
22: Care Forum, correct?
23: A. And pharmacy groups, yes,
24: among others, yes.

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00294

01: Q. Then the executive committee
02: approved them, correct?
03: A. That's correct.
04: Q. And then there's these DEA
05: meetings that we just discussed, right?
06: A. Correct.
07: Q. April 15th, June 4th, and
08: Ms. Ducca said she didn't make minutes of
09: the September 5th one, agreed?
10: A. Yes.
11: Q. And then you get the letter
12: on October 23rd that we looked at
13: Exhibit 28?
14: A. Yes.
15: MR. PIFKO: We can take a
16: break.
17: THE VIDEOGRAPHER: The time
18: is 2:12 p.m. We are going off the
19: record.
20: (Short break.)
21: THE VIDEOGRAPHER: The time
22: is 2:29 p.m. We are back on the
23: record.
24: (Document marked for

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00295
01: identification as Exhibit
02: HDA-Kelly-30.)
03: BY MR. PIFKO:
04: Q. I'm handing you what's
05: marked Exhibit 30. It's an e-mail,
06: two-page e-mail with an attachment,
07: one-page attachment, Bates-labeled
08: HDA_MDL_000080421 through 423.
09: Take a minute to review it
10: and let me know when you're done.
11: Are you ready?
12: A. Yes.
13: Q. Are you familiar with this
14: discussion; you were at HDA at this time,
15: correct?
16: A. I was at HDA at this time,
17: yes. I am not familiar with this
18: particular e-mail, but I understand the
19: correspondence between the communications
20: department and -- and Anita Ducca.
21: Q. Okay. So Farah Qureshi, am
22: I -- am I saying that right?
23: A. Yes.
24: Q. She's a communications

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00297
01: diversion that is attached as the last
02: page of Exhibit 30. Agree?
03: MR. WEINSTEIN: Objection to
04: form.
05: THE WITNESS: Yes.
06: BY MR. PIFKO:
07: Q. And then Anita Ducca
08: provides some comments in this e-mail
09: dated Wednesday June 12, 2013. Agree?
10: A. Yes.
11: Q. And then she actually
12: attaches the redline that's -- and the
13: redline is what is the second page,
14: agree?
15: A. Yes, it appears so.
16: Q. Okay. So one of Anita's
17: comments is, she says, "Although there
18: are some examples of what our members do,
19: I'm hesitant to include anything like
20: that."
21: You see that in the third
22: paragraph?
23: A. Yes.
24: Q. And then she says, "Not all

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00296
01: manager?
02: A. Yes.
03: Q. So she is responsible for
04: providing initial drafts of public --
05: public statements that HDA might post?
06: A. It's --
07: MR. WEINSTEIN: Objection to
08: form.
09: THE WITNESS: Primarily just
10: with what goes up onto the
11: internet and what gets -- public
12: facing. And all the policy
13: documents are developed usually
14: inside the government affairs
15: department.
16: BY MR. PIFKO:
17: Q. Okay. So Farrah's job is to
18: draft materials that will be on HDA's
19: website?
20: A. Yes. And kind of, you know,
21: position them and pretty them up for the
22: website.
23: Q. Okay. So she prepares this
24: one-pager on prescription drug abuse and

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00298
01: our members are doing what HD Smith
02: does."
03: Do you see that?
04: A. Yes.
05: Q. "If DEA sees this, which
06: they are likely to at some point, they
07: may question why all our members aren't
08: doing it."
09: Do you see that?
10: A. Yes.
11: Q. "Sort of like how they took
12: our ICG and included it in their legal
13: filing against Walgreens Distribution
14: Center, claiming that there was an
15: industry standard that Walgreens should
16: have known about and been following."
17: Do you see that?
18: A. I do.
19: Q. There were some frustration
20: at HDA that DEA had cited the industry
21: compliance guidelines as an industry
22: standard and used them against Walgreens?
23: MR. WEINSTEIN: Objection to
24: form.

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00299

01: THE WITNESS: I don't know
02: that there was frustration. I
03: think we were -- we were slightly
04: concerned that a document that was
05: voluntary guidelines was cited in
06: a -- in a proceeding by DEA
07: against a non-HD member or non --
08: at that point still HDMA or HDA at
09: that point. So that was the
10: concern.
11: BY MR. PIFKO:
12: Q. I'm handing you what's
13: marked as Exhibit 31.
14: (Document marked for
15: identification as Exhibit
16: HDA-Kelly-31.)
17: BY MR. PIFKO:
18: Q. This is a chronology of
19: HDMA/HDA executive committee and board of
20: directors' drug abuse and diversion
21: discussions at meetings and conference
22: calls. It's dated January 2, 2018.
23: It's kind of lengthy. I
24: just want to point you to a particular

p. 00299

00301

01: Q. Do you have any reason to
02: dispute that the statements in here are
03: accurate with respect to discussions at
04: the board meetings?
05: A. No, I have no reason to
06: dispute that.
07: Q. Okay. I want to direct you
08: to Page 7 which is HDA_MDL_00015936. Are
09: you there?
10: A. Yes.
11: Q. Second full paragraph, or
12: look at -- second paragraph here.
13: A. Yep.
14: Q. Second sentence it says,
15: "DEA has been referring to the industry
16: compliance guidelines on suspicious
17: orders and certain legal documents
18: resulting in the implication that it is
19: an industry standard. Since these
20: guidelines were never intended to
21: constitute a standard, they have been
22: taken down from the HDMA website at the
23: direction of the government public policy
24: council."

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00300

01: passage that's relevant to the suspicion
02: about the industry compliance guidelines
03: on Page 7.
04: And for the record,
05: Exhibit 31 is Bates-labeled
06: HDA_MDL_000155930 through 155946.
07: MR. WEINSTEIN: 47 actually.
08: MR. PIFKO: 47. Sorry.
09: Thanks.
10: BY MR. PIFKO:
11: Q. And these notes were
12: prepared by Ms. Ducca. I want to turn
13: your attention to Page 7.
14: MR. WEINSTEIN: Was that a
15: question or was that a statement?
16: MR. PIFKO: No, I'm stating
17: to you.
18: THE WITNESS: I don't know
19: that these were prepared. This is
20: a summary of -- of board minutes,
21: I believe. So it was -- I don't
22: think this was prepared by Anita
23: Ducca.
24: BY MR. PIFKO:

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00302

01: Did I read that correctly?
02: A. Yes, you did.
03: Q. Is that consistent with your
04: understanding of --
05: A. Yes, it is.
06: Q. -- why the guidelines were
07: taken down?
08: A. Yes, it is.
09: (Document marked for
10: identification as Exhibit
11: HDA-Kelly-32.)
12: BY MR. PIFKO:
13: Q. Handing you what's marked as
14: Exhibit 32. It's a two-page document
15: Bates-labeled HDA_MDL_00081415 and 416.
16: Take a minute to review this
17: and let me know when you're done.
18: A. Okay.
19: Q. I just wanted to direct your
20: attention to second paragraph on the
21: first page.
22: "The regulatory affairs
23: committee and federal government affairs
24: committee told its members that there was

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00303

01: some consideration about updating the
02: guidelines, but ultimately it was decided
03: that they would be replaced with a
04: statement to the effect that the industry
05: is very committed to compliance."
06: And there was a draft that
07: was exchanged with members, agree?
08: MR. WEINSTEIN: Objection to
09: form.

10: THE WITNESS: Yes, that's
11: what this says.

12: BY MR. PIFKO:

13: Q. And that's what happened?
14: A. I don't recall exactly what
15: the process was between the ICGs coming
16: down and a statement going up in its
17: stead. But again, I have no reason to
18: doubt that this process described here is
19: accurate.

20: Q. Handing you what's marked as
21: Exhibit 33.
22: (Document marked for
23: identification as Exhibit
24: HDA-Kelly-33.)

p. 00303

00305

01: Government Accountability Office about
02: the -- its concerns about the DEA,
03: correct?
04: MR. WEINSTEIN: Objection to
05: form.
06: THE WITNESS: I don't know
07: if that was part of that. I
08: didn't -- was that part of that?
09: BY MR. PIFKO:
10: Q. Irrespective of that
11: document, I'm just asking you --
12: A. It is --
13: Q. -- if that was another
14: tactic that HDA was investigating?
15: MR. WEINSTEIN: Objection to
16: form.
17: THE WITNESS: Again, we
18: don't have the ability to launch
19: GAO investigations, but we can
20: talk to members of Congress who
21: may think that's a correct course
22: of action.
23: BY MR. PIFKO:
24: Q. Okay. And so that was

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00304

01: BY MR. PIFKO:
02: Q. For the record Exhibit 33 is
03: a Word document that was -- file name --
04: name GAO Meeting on DEA Draft, TPs,
05: 092010. It's Bates-labeled HDMA -- or
06: sorry, HDA_MDL_000139905 to 000139910.
07: Take a minute to review it and let me
08: know when you're done.
09: A. Okay.
10: Q. You done?
11: A. Yes.
12: Q. So if you recall, we were
13: looking earlier at a document, that
14: document about the strategy for testimony
15: on the Hill. Do you recall that?
16: A. Yes, I do.
17: Q. And one of the tactics that
18: was discussed there was getting a
19: congressperson to talk to the DEA to
20: address the industry's concerns. Do you
21: recall that?
22: A. I do.
23: Q. Another tactic that HDA was
24: considering was communicating with the

p. 00304

00306

01: something that HDA was exploring about
02: whether there could be a dialogue with
03: GAO about the industry's concerns about
04: the DEA, correct?
05: MR. WEINSTEIN: Objection to
06: form.
07: THE WITNESS: Again I don't
08: know if we -- if we specifically
09: requested that. I know that this
10: GAO report was requested by
11: members of Congress.
12: BY MR. PIFKO:
13: Q. Okay. These are talking
14: points about the industry's concerns that
15: would be presented at the GAO, correct?
16: A. Correct.
17: Q. So, this talks about, I'm on
18: the second page of the document. It
19: first says, "Background on HDMA, who we
20: represent, show the graphic of wholesale
21: distribution we have online, number of
22: members, et cetera."
23: So in connection with the
24: discussion, there would have been a

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00307

01: discussion about who the members are that
02: are represented by HDA, correct?
03: MR. WEINSTEIN: Objection to
04: form.
05: THE WITNESS: Yes.
06: BY MR. PIFKO:
07: Q. And then this identifies
08: recent concerns. Do you see that
09: discussion in Section 4 here?
10: A. Yes, I see Section 4.
11: Q. It says, "Recently DEA has
12: exerted extreme pressure on wholesale
13: distributors to take controlled
14: substances suspicious order
15: responsibilities much further."
16: Do you see that?
17: A. I do.
18: Q. Do you agree that was a
19: concern from HDA and its distributor
20: members?
21: MR. WEINSTEIN: Objection to
22: form.
23: THE WITNESS: It was.
24: BY MR. PIFKO:

p. 00307

00309

01: was -- that was an event or a
02: process that DEA had undertaken.
03: I have no reason to doubt that
04: that was part of the pattern of
05: concern.
06: BY MR. PIFKO:
07: Q. And then another part of
08: that concern was that that action was
09: followed by revoking several
10: registrations in 2007, agreed?
11: A. That's what is stated, yes.
12: Q. And then it says, "HDA went
13: to great lengths to seek resolution with
14: DEA." And then it's got some bullet
15: points. Some of them are discussing the
16: industry compliance guidelines we just
17: discussed, agree?
18: A. Yes.
19: Q. And then in all bold, all
20: caps, it says, "Despite these efforts,
21: DEA has revoked another wholesale
22: distributor registration spring 2010."
23: Do you see that?
24: A. I do.

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00308

01: Q. And then it gives bullet
02: points elaborating on that concern,
03: agree?
04: A. It appears to, yes.
05: Q. And the first one is, "DEA
06: invited members of the distribution
07: industry, firm by firm to a meeting where
08: DEA point blank told them that they
09: should identify customers who are selling
10: for illicit purposes, e.g., pill mills, or
11: illicit internet pharmacies such as those
12: filling orders without a prescription."
13: Do you see that?
14: A. I do.
15: Q. So that was part of the
16: basis for the HDA and its members'
17: concerns about DEA's pressures to take
18: controlled substances order
19: responsibilities further?
20: MS. WICHT: Objection to
21: form.
22: MR. WEINSTEIN: Objection to
23: form.
24: THE WITNESS: Again, that

p. 00308

00310

01: Q. So the DEA's revoking or
02: suspending registrations, was a
03: significant concern for HDA and its
04: members?
05: MR. WEINSTEIN: Objection to
06: form.
07: THE WITNESS: Yes.
08: BY MR. PIFKO:
09: Q. If you go to the page --
10: they are not numbered here --
11: HDA_MDL_000139907. There's a heading,
12: "Key Concerns."
13: A. I see it.
14: Q. So this summarizes key
15: concerns that HDA and its members had
16: with respect to the DEA's enforcement
17: activities, correct?
18: MR. WEINSTEIN: Objection to
19: form.
20: THE WITNESS: Yes, at the
21: time.
22: BY MR. PIFKO:
23: Q. So one of them is, it says,
24: "It's unreasonable for DEA to expect a

p. 00310

00311

01: distributor to seek information about
02: pharmacies that they are barred from,
03: either through confidential business
04: practices or legal restrictions, e.g.,
05: HIPAA."
06: Do you see that?
07: A. Yes, I do.
08: Q. That was a key concern?
09: MS. CHARLES: Objection to
10: form.
11: THE WITNESS: Again, this
12: means that they were unreasonable
13: for DEA to expect distributors to
14: get prescribing information that
15: would have been HIPAA protected.
16: BY MR. PIFKO:
17: Q. And then it says under here,
18: "DEA has asked distributors where
19: pharmacies' prescriptions came from, also
20: to research the pharmacies' customer
21: base.
22: So was that -- that was the
23: basis for that concern?
24: A. I think that's part of the

p. 00311

00313

01: Q. I want to direct your
02: attention back to Exhibit 31, on the
03: first page of it. Are you there?
04: A. I am.
05: Q. There's a note about a
06: conference call with the executive
07: committee on April 6, 2012.
08: Do you see that?
09: A. Yes.
10: Q. It says, "President John
11: Gray thanked the executive" -- "thanked
12: the executive committee members for
13: agreeing to participate in a conference
14: call to address recent activity with
15: respect to suspicious order monitoring
16: and the role of healthcare distributors."
17: Do you see that?
18: A. I do.
19: Q. And then it says, "HDMA has
20: testified before Congress and prepared an
21: amicus brief for filing with the federal
22: court of appeals in the Cardinal v.
23: Holder litigation."
24: Do you see that?

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00312

01: concern, yes.
02: Q. Then it says, "Even if the
03: distributor does their due diligence
04: regarding a customer, there's no
05: guarantee that the pharmacy will tell the
06: truth."
07: That was another concern?
08: A. That is -- that is a
09: concern, yes.
10: Q. Then here it says, again,
11: "DEA used an extreme tactic by suspending
12: a license. This action is intended for
13: when there is an imminent threat to the
14: public health and safety."
15: Do you see that?
16: A. Yes.
17: Q. So again, this tactic of
18: suspending or revoking registrations was
19: a critical concern for HDMA and its
20: members, correct?
21: MR. WEINSTEIN: Objection to
22: form.
23: THE WITNESS: Yes.
24: BY MR. PIFKO:

p. 00312

00314

01: A. I do.
02: Q. HDA's members authorized HDA
03: to file that amicus brief in the federal
04: court of appeals, correct?
05: A. They did.
06: Q. Okay. And then it says
07: here, "Chairman Moody and Vice Chairman
08: Neu expressed concern about the trend of
09: recent developments and thought it time
10: for executive committee to review recent
11: events and plot a course going forward."
12: Do you see that?
13: A. I do.
14: Q. Okay. You understand
15: Chairman Moody is from Cardinal?
16: A. No. Chairman Moody at the
17: time was Dave Moody from North Carolina
18: Mutual.
19: Q. Okay. That is another
20: distributor member?
21: A. That is.
22: Q. Okay. And Chairman Neu was
23: from AmerisourceBergen?
24: A. Vice Chairman Neu at the

p. 00314

00315
01: time was from AmerisourceBergen, yes.
02: Q. Vice chairman.
03: (Document marked for
04: identification as Exhibit
05: HDA-Kelly-34.)
06: BY MR. PIFKO:
07: Q. Handing you what's marked as
08: Exhibit 34. Take a minute to review that
09: and let me know when you're done.
10: A. Okay.
11: Q. To put some time frame
12: context in this, are you aware that on
13: February 6, 2012, the DEA had announced
14: that it suspended the license of Cardinal
15: Health's Lakeland distribution center?
16: MR. WEINSTEIN: Objection to
17: form.
18: THE WITNESS: That sounds
19: familiar.
20: BY MR. PIFKO:
21: Q. Okay. And so I just read
22: you from Exhibit 31 about the conference
23: call that's a few months later, two
24: months after that happened. Do you

p. 00315

00317
01: form.
02: THE WITNESS: Yes.
03: BY MR. PIFKO:
04: Q. And so then, there was a
05: decision that they needed to plot a
06: course going forward as it says in
07: Exhibit 31, agree?
08: A. Yes, that's what it says.
09: Q. Okay. So after that call,
10: John Gray says here that he met with
11: legal counsel Bob Barnett and Richard
12: Cooper from Williams & Connolly in
13: Washington DC, agreed?
14: A. Yes.
15: Q. And he comments -- I'm
16: reading from Exhibit 34 -- "Both
17: attorneys were very helpful several years
18: ago in initializing our original meetings
19: with DEA after the first outbreak of
20: ISOs" -- those are suspension orders,
21: correct?
22: A. Correct.
23: Q. "Given their experience and
24: knowledge of the political and legal

p. 00317

00316
01: recall we just discussed that?
02: A. Yes.
03: Q. And so Exhibit 34 says,
04: "After our last conference call on
05: April 6th" -- referring to that
06: conference call, agreed?
07: A. Yes. April 20th, yeah.
08: Q. Okay. And for the record
09: Exhibit 34 is an e-mail from John Gray
10: dated Friday, April 20, 2012, to Ken
11: Couch, Dale Smith, David Neu, Paul
12: Julian, Mike Kaufmann, David Moody and
13: Ted Scherr, copying Richard Frank from
14: HDA's outside counsel.
15: Agree?
16: A. Yes.
17: Q. Sorry, I can't remember if I
18: read the Bates number for this one.
19: 00 -- HDA_MDL_00215234 to 236.
20: So at this executive
21: committee conference call, there was
22: concerns raised by the members again
23: about DEA's enforcement activity. Agree?
24: MR. WEINSTEIN: Objection to

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00318
01: aspects of dealing with DEA, we updated
02: them on the industry's recent concerns
03: with DEA's latest efforts to thwart drug
04: diversion and abuse. Attached is a brief
05: summary of our discussion and conclusions
06: with several possible courses of action
07: HDMA could take. The entire list of
08: ideas is not necessarily mutually
09: exclusive, but does represent a wide
10: range of political actions the
11: association and the industry may consider
12: in an effort to alter the present
13: direction DEA is taking with respect to
14: suspicious order monitoring."
15: Did I read that correctly?
16: A. You -- potential options,
17: actions, not political actions.
18: Q. Sorry.
19: A. That's okay.
20: Q. So these are the same Bob
21: Burnett and Richard Cooper that we saw
22: who were participating in the meetings
23: with DEA with respect to the industry
24: compliance guidelines, correct?

p. 00318

00319

01: A. Correct.
02: Q. And then the attached, the
03: following three pages of Exhibit 34 is
04: this document that says, according to the
05: e-mail, it's, "DEA options memorandum,
06: J. Gray edits," do you see that on the
07: first page? On the header of the e-mail,
08: that's what the attached document is?
09: A. Yes, yes, yes, yes, yes.
10: Q. So then it's a memo from
11: Mr. Gray to the HDMA executive committee
12: dated April 20, 2012. Agree?
13: A. Yes.
14: Q. And who is on the executive
15: committee at this time?
16: A. At this time it is Ken Couch
17: from Smith Drug, Dale Smith from
18: HD Smith, Dave Neu from
19: AmerisourceBergen, Paul Julian from
20: McKesson, Mike Kaufmann from Cardinal,
21: David Moody from North Carolina Mutual
22: and Ted Scherr from Dakota Drug.
23: Q. And so then this -- the
24: first paragraph says, again, some of the

p. 00319

00321

01: process could help at least get
02: some type of notice and comment
03: back and forth with the DEA and
04: maybe securing that. If we
05: weren't successful in having the
06: DEA do that through their notice
07: and comment process, to maybe
08: request that legislatively.
09: BY MR. PIFKO:
10: Q. And what specifically would
11: the legislation include?
12: MR. WEINSTEIN: Objection to
13: form, foundation, scope.
14: THE WITNESS: Well, again,
15: we did -- we didn't get into
16: specifics of -- of what that
17: legislation -- we never drafted
18: legislation at that point in time.
19: But we were looking at
20: basically their interaction with
21: the registrant community on
22: suspicious orders.
23: BY MR. PIFKO:
24: Q. Later down the road you

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00320

01: same stuff that's in the e-mail. And
02: then the second paragraph says,
03: "Mr. Barnett and Mr. Cooper felt that new
04: legislation to specifically address our
05: concerns with DEA was highly unlikely to
06: be successful due to limited momentum in
07: that direction."
08: Do you see that?
09: A. I do.
10: Q. You understood that one of
11: the things HDA and its members were
12: considering was new legislation to
13: address the concerns with DEA?
14: MR. WEINSTEIN: Objection to
15: form.
16: MR. CRAWFORD: Objection to
17: form.
18: THE WITNESS: We had -- we
19: had -- again, one of the concerns
20: we had with the provisions that
21: DEA was implementing is that there
22: was no due process.
23: And so we thought that
24: possibly requesting legislative

p. 00320

00322

01: ultimately did participate in what became
02: the Marino/Blackburn bill, correct?
03: A. That's correct.
04: MS. WICHT: Object to the
05: form of the question.
06: BY MR. PIFKO:
07: Q. Was that an outcrop of this
08: discussion?
09: MR. WEINSTEIN: Objection to
10: form.
11: THE WITNESS: Not this
12: specific discussion.
13: BY MR. PIFKO:
14: Q. Okay. But it -- it grew
15: from these same concerns about DEA's
16: enforcement action and suspension of
17: licenses, correct?
18: MR. WEINSTEIN: Objection to
19: form.
20: MS. CHARLES: Objection.
21: BY MR. PIFKO:
22: Q. Or registrations, sorry?
23: MR. WEINSTEIN: Same
24: objection.

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00323

01: THE WITNESS: It was part of
02: that, yes.
03: BY MR. PIFKO:
04: Q. Okay. So another thing
05: Mr. Gray writes in this memo is that
06: "Paul Barnett and Rich Cooper from
07: Williams & Connolly felt that the
08: industry may be better off asserting DEA
09: actions by taking even stronger
10: compliance measures."
11: Do you see that?
12: A. Yes.
13: Q. Did I read that correctly?
14: A. You did.
15: Q. Were you part of these
16: discussions?
17: A. I was in this meeting at
18: Williams & Connolly, yes.
19: Q. Okay. And so one of the
20: recommendations they said is that HDA's
21: members could avert action by improving
22: their compliance systems?
23: MR. WEINSTEIN: Objection to
24: form.

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00324

01: THE WITNESS: That's -- I
02: mean, it says that they felt they
03: were better off averting DEA
04: actions by taking even stronger
05: compliance measures. That's
06: what's written in the memo.
07: BY MR. PIFKO:
08: Q. And that's what was
09: discussed at the meeting? You said you
10: were there?
11: A. I was there, yes.
12: Q. And that's consistent with
13: what was discussed there?
14: A. Yes.
15: Q. Let's go to Page 2 of the
16: attachment, I guess 3 of the document.
17: One of the other potential -- it has
18: other potential actions discussed here.
19: Do you see that?
20: A. I do.
21: Q. "Update HDMA industry
22: compliance guidelines." That was
23: something else that was being discussed
24: at that time?

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00325

01: A. Yes.
02: Q. And we know ultimately from
03: Exhibits 30 and 31 that -- that
04: ultimately the ICGs were replaced with a
05: statement on diversion, rather than
06: updated?
07: A. Yes.
08: Q. Another potential action is
09: to re-file the HDMA amicus brief in
10: Cardinal Health v. DEA, do you see that?
11: A. I do. In the appellate
12: case.
13: Q. So are you familiar with the
14: procedure? Why was there a need to
15: re-file that brief?
16: MR. WEINSTEIN: Objection to
17: form. Foundation.
18: THE WITNESS: Again, I'm not
19: familiar -- I don't know what the
20: discussion was. That was a
21: discussion with outside counsel
22: about that, and with the board.
23: So I don't -- I don't know what
24: the rationale was for that.

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00326

01: BY MR. PIFKO:
02: Q. Are these notes consistent
03: with your understanding of the
04: discussions that happened at that meeting
05: since you were there?
06: MR. WEINSTEIN: Objection to
07: form.
08: THE WITNESS: Yes.
09: BY MR. PIFKO:
10: Q. Okay. Another potential
11: action, again going to Page 2 of the
12: notes, is, "Seek guidance from a
13: well-respected public relations firm to
14: improve industry image."
15: This was something else that
16: was considered?
17: A. Yes.
18: Q. Did you ever move forward
19: with that option?
20: A. We did.
21: Q. And who did you retain?
22: A. Processwise, after this
23: meeting, we've been through -- we've been
24: engaged with several public relations

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00327

01: firm. But I think this one led to an
02: initial engagement with APCO.
03: Q. And they developed the
04: crisis playbook, right?
05: A. That -- yes, that was their
06: development, yes. I don't know if that's
07: the specific name of it. But it was --
08: Q. But you're familiar with
09: that document?
10: A. Yes, that they developed,
11: yes.
12: Q. Okay. Another option here
13: is, "Petition DEA to put their
14: expectations into a regulation."
15: Can you explain what that
16: was?
17: A. Again, that was -- that was
18: the -- basically the process of -- you
19: know, the letters constituted the only
20: directives that we were getting from DEA
21: at the time, the letter to the
22: registrants. There was no process for
23: notice and comment in the development of
24: those letters. They were just basically

p. 00327

00329

01: effective in this regard but would
02: unlikely" -- "be unlikely to happen prior
03: to the 2012 elections."
04: A. That's what it says, yes.
05: Q. How would you use a
06: congressional hearing to achieve the same
07: things that a legal journal article would
08: achieve?
09: A. I'm not exactly sure why --
10: why that was typed up that way. But,
11: again, it was to basically get some of
12: these concerns addressed in an open forum
13: for kind of probative discussion about,
14: you know, concerns we had and maybe
15: suggestions about processes that would
16: kind of more enlist the support of the
17: registrant community in addressing
18: suspicious orders.
19: Q. Were you involved in
20: subsequent phone discussions or in person
21: discussions with HDA's executive
22: committee after this memo was sent out?
23: MR. WEINSTEIN: Objection to
24: form.

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00328

01: delivered.
02: We thought that if we
03: basically petitioned for a regulation to
04: go through a notice and comment
05: development process where the DEA would
06: basically draft a regulation, they would
07: notice it for public comment, there would
08: be public comment. They would review the
09: public comments. They would then
10: consider the public comment and finalize
11: the regulation.
12: But you would at least have
13: a process by which you could provide
14: concerns, suggestions, et cetera to the
15: DEA for the development of that
16: regulation.
17: Q. Another thing is to develop
18: a legal journal article concerning the
19: ambiguity of DEA expectations and
20: diversion prevention tactics. That was
21: something else that you discussed?
22: A. We -- it did, yes.
23: Q. And it said, "A
24: congressional hearing may be more

p. 00328

00330

01: THE WITNESS: I don't recall
02: the specific process of what
03: happened after this. I know that
04: this was something that the
05: executive committee asked us to
06: do. We did. We followed up with
07: them. We probably reported on it
08: at the next executive committee
09: meeting.
10: BY MR. PIFKO:
11: Q. But do you recall having any
12: discussions with the executive committee
13: members about these options?
14: MR. WEINSTEIN: Objection to
15: form.
16: THE WITNESS: No. Again,
17: not prior to the executive
18: committee meeting.
19: BY MR. PIFKO:
20: Q. Are you aware that -- of
21: whether any of the executive committee
22: members asked how they could improve
23: their compliance measures consistent with
24: the advice that Bob Barnett and Rich

p. 00330

00331

01: Cooper from Williams & Connolly provided?
02: MR. WEINSTEIN: Objection to
03: form. Foundation. Scope.
04: THE WITNESS: I'm not aware
05: of any specifics, suggestions or
06: conversations.
07: BY MR. PIFKO:
08: Q. To your knowledge did any of
09: them ask if there would be any
10: suggestions on how their compliance
11: efforts could be improved?
12: MR. WEINSTEIN: Objection to
13: form. Foundation. Scope.
14: THE WITNESS: Again, I don't
15: know that anybody asked. We did
16: provide some suggestions that were
17: provided by Mr. Cooper and
18: Mr. Barnett. But again, I don't
19: recall. And the correspondence
20: would have been with Mr. Gray
21: directly anyhow.
22: (Document marked for
23: identification as Exhibit
24: HDA-Kelly-35.)

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00333

01: committee, federal government affairs
02: committee, individuals, and then to
03: basically brainstorm some suggestions for
04: additional things that we could do to
05: continue to move forward on addressing
06: suspicious orders and improving
07: interaction with the DEA.
08: Q. So that task force is an
09: outcrop of some of the types of
10: discussions that you had in Exhibit 34?
11: A. Yeah. It's not specifically
12: referenced here. But yeah, it's just an
13: ongoing discussion and dialogue with the
14: membership about what we can do to
15: improve.
16: Q. Who was on that task force
17: as far as the HDA's distributor members?
18: A. So if you look at the top,
19: AmerisourceBergen, Cardinal Health,
20: Mutual Drug, Smith Drug, HD Smith, Henry
21: Schein, I think was at one point
22: involved.
23: Q. McKesson?
24: A. McKesson, sorry, yes. And

p. 00333

00332

01: BY MR. PIFKO:
02: Q. I'm handing you what's
03: marked as Exhibit 35. It's an e-mail
04: from you dated December 19, 2013,
05: Bates-labeled CAH_MDL2804_01110712
06: through 715.
07: Take a moment to review this
08: and let me know when you're done.
09: A. Okay.
10: Q. At some point a drug
11: diversion DEA strategy task force was
12: formed, correct?
13: A. Yes.
14: Q. Are you familiar with the
15: formation of that task force?
16: A. I am.
17: Q. Were you involved in the
18: formation of that task force?
19: A. We were. I was.
20: Q. When was that formed?
21: A. I want to say in 2013 at
22: some point. It was a amalgam of a
23: variety of different committees that had
24: been involved. Regulatory affairs

p. 00332

00334

01: then we had a -- after we had engaged
02: APCO at the time there, they came and
03: participated.
04: Q. And so you had regular
05: meetings with this task force?
06: A. This -- I believe this task
07: force met once.
08: Q. Okay. And so this is a list
09: of action items that came out of the task
10: force meeting?
11: A. Recommendations, yes.
12: Q. Okay. And then the attached
13: document, summary of recommendations?
14: A. Right.
15: Q. From December 11, 2013, task
16: force meeting. That's a summary of the
17: items that the group came up with that
18: you could move forward with?
19: MR. WEINSTEIN: Objection to
20: form.
21: THE WITNESS: Yes.
22: Sorry.
23: Yes, with the -- the
24: specific action items highlighted.

p. 00334

00335
01: BY MR. PIFKO:
02: Q. And you typed this up?
03: A. I believe I typed the
04: e-mail, and then the notes were kind of
05: probably a shared product of the
06: government affairs staff that
07: participated.
08: Q. Okay. But you ultimately
09: sent it out to everybody?
10: A. I sent it out, yes.
11: Q. Did you have an official
12: title or role with this task force, like
13: chairman or --
14: A. No.
15: Q. -- coordinator?
16: A. No, there was -- and again
17: it was an ad hoc group of various
18: members. It was set up to do one thing,
19: and this was the one thing.
20: Q. So going to the attachment,
21: CAH_MDL2804_01110714. Are you there?
22: A. I am.
23: Q. So Item 2 is, "Address
24: specific challenges and interactions

p. 00335

00337
01: to Prevent Abuse of Medicines?
02: A. That was a coalition that
03: formed, I want to say in about 2012, to
04: address abuse issues, kind of across the
05: supply chain. So they had formed -- the
06: American Medical Association, the members
07: that were listed there were participants.
08: Cardinal Health had suggested possibly
09: including HDA as a member, because other
10: associations were involved.
11: THE VIDEOGRAPHER:
12: Mr. Kelly, you keep hitting --
13: THE WITNESS: I'm sorry.
14: BY MR. PIFKO:
15: Q. So then Item 2 says,
16: "Address specific challenges and
17: interactions with DEA."
18: Do you see that?
19: A. I do.
20: Q. Then it says, "Issue
21: statement of support for Marino/Blackburn
22: legislation when introduced."
23: Do you see that?
24: A. I do.

p. 00337

00336
01: with" -- "with DEA."
02: Do you see that?
03: A. Yes.
04: Q. So you have this broken out
05: into different types of communications
06: like one with the media, public
07: officials, another with DEA, and another
08: with a branding campaign; is that
09: correct?
10: MR. WEINSTEIN: Objection to
11: form.
12: THE WITNESS: Yeah.
13: BY MR. PIFKO:
14: Q. Okay. Sorry, I pointed you
15: to 2, but I want to ask you about 1 for a
16: minute.
17: A. Okay.
18: Q. So in 1, there's a
19: discussion about joining with various
20: other industry groups?
21: A. Mm-hmm.
22: Q. Is that correct?
23: A. Yes.
24: Q. Okay. What's the Alliance

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00338
01: Q. Okay. So that hadn't yet
02: been introduced at this time?
03: A. I don't know the specific
04: introduction date, but I would deduce
05: from this that obviously it had not.
06: Q. Okay. Was the -- that
07: legislation drafted out of the HDMA?
08: A. No. I believe
09: Mr. Blackburn -- or I'm sorry, Mr. Marino
10: was moving forward with that issue, had
11: requested feedback from a variety of
12: constituencies, and was in the process of
13: kind of fleshing it out.
14: Q. When was the first time you
15: became aware of that bill or that
16: legislation?
17: A. It -- it might have been at
18: this -- at this meeting. One of our
19: member companies had been contacted by
20: Mr. Marino about participating in the --
21: in the kind of the general drafting
22: process of -- of that bill. And it was
23: suggested that we -- we work with -- or
24: HDA work with Congressman Marino and

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00339
01: Congresswoman Blackburn.
02: Q. Do you know which member
03: company it was?
04: A. It was Cardinal.
05: Q. Okay. So Mr. Marino had
06: reached out to Cardinal and asked them to
07: assist in drafting this bill?
08: A. That's my understanding.
09: Q. And then they reached out to
10: you and asked HDA to participate?
11: A. They did.
12: Q. And did HDA end up providing
13: any drafting on the bill?
14: A. We provided feedback on
15: drafts that they -- they would -- that
16: they would basically share drafts with
17: us. I don't know if it was in advance of
18: the actual introduction. But they go
19: through iterative processes of kind of
20: taking comments and providing subsequent
21: drafts. We did participate in that
22: process.
23: Q. Do you know who -- who
24: specifically at Cardinal did you interact

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00341
01: for certain.
02: BY MR. PIFKO:
03: Q. Do you know if Linden Barber
04: was involved in the Marino/Blackburn
05: bill?
06: MR. WEINSTEIN: Same
07: objections.
08: MS. WICHT: Object to form.
09: THE WITNESS: I don't know
10: initially. It was a multi-year
11: process.
12: BY MR. PIFKO:
13: Q. Do you know if any other HDA
14: distributor members were involved in
15: discussions with Marino at that time
16: concerning the bill?
17: MS. WICHT: Objection to
18: form.
19: MR. WEINSTEIN: Objection to
20: form, foundation, scope.
21: THE WITNESS: At that time I
22: do not.
23: BY MR. PIFKO:
24: Q. How about later?

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00340
01: with on that issue?
02: MS. WICHT: Objection to
03: form.
04: THE WITNESS: Connie
05: Woodburn was the government
06: affairs person for Cardinal at the
07: time.
08: BY MR. PIFKO:
09: Q. Okay. But did you interact
10: with anyone else from Cardinal?
11: A. Not specifically with regard
12: to this.
13: Q. Okay. Did -- do you -- do
14: you know, were there other people who
15: maybe you didn't talk to but that would
16: have been copied on e-mails or there are
17: things would have been forwarded from
18: Cardinal with respect to the
19: Marino/Blackburn bill?
20: MS. WICHT: Objection to
21: form.
22: MR. WEINSTEIN: Objection to
23: form, foundation, scope.
24: THE WITNESS: I can't say

p. 00340

00342
01: MS. WICHT: Objection to
02: form.
03: MR. WEINSTEIN: Same
04: objections.
05: THE WITNESS: Well, as soon
06: as -- as soon as HDA basically
07: endorsed the -- the initiative, I
08: think the entire membership was
09: supportive of the -- the prospect
10: of that legislation.
11: BY MR. PIFKO:
12: Q. Okay. And obviously the
13: entire member -- or the -- the members we
14: just discussed here having been involved
15: with this drug diversion task force all
16: knew about it because it was discussed at
17: this meeting, correct?
18: MR. WEINSTEIN: Objection to
19: form.
20: MS. WICHT: Foundation.
21: THE WITNESS: Correct.
22: BY MR. PIFKO:
23: Q. So it says here, "This
24: legislation would establish definitions

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00343

01: and parameters for specific provisions in
02: the Controlled Substances Act pertaining
03: threats to 'public health and safety' and
04: 'imminent danger.'
05: "In addition, this
06: legislation would allow DEA registrants
07: the opportunity to submit a corrective
08: action plan to address specific concerns
09: that could otherwise lead to the
10: suspension or revocation of a
11: registration."
12: Did I read that correctly?
13: A. You did.
14: Q. Is that consistent with your
15: understanding about what this bill would
16: do or legislation would do?
17: MR. WEINSTEIN: Objection to
18: form.
19: THE WITNESS: It is. There
20: was another provision ultimately
21: of the bill. But it was a
22: draft -- a report from the
23: government on the effectiveness of
24: the government's efforts to

p. 00343

00345

01: constitutes imminent danger.
02: BY MR. PIFKO:
03: Q. If we go to the next page of
04: your notes. Another action item that
05: this task force was working on was Item
06: D, "Anticipate and develop responses to
07: Marino/Blackburn opponents"?
08: A. I see that.
09: Q. That was something that this
10: task force was working on, correct?
11: A. Well, again, it wasn't one
12: of the action items. But it was -- it
13: basically was something that we
14: discussed. It was, you know, how do
15: we -- how do we explain what this does if
16: people are concerned that it's somehow
17: diminishing the capacity of the DEA.
18: Q. Item 3 here is, "Engage in
19: initial HDMA public relations branding
20: campaign."
21: Do you see that?
22: A. I do.
23: Q. Item C there says, "Utilize
24: material prepared by APCO to begin

p. 00345

00344

01: address prescription drug abuse
02: and diversion.
03: BY MR. PIFKO:
04: Q. Okay. So it's your
05: understanding there were changes to the
06: requirements for suspending a
07: registration, and there was another
08: component to the legislation that
09: involved a report?
10: MR. WEINSTEIN: Objection to
11: form.
12: BY MR. PIFKO:
13: Q. Is that correct?
14: MR. WEINSTEIN: Same
15: objection.
16: THE WITNESS: So, basically
17: the crux of it was to provide a
18: definition for the threshold for
19: immediate suspension orders.
20: Which was not anywhere in law.
21: The immediate -- the immediate --
22: imminent danger was not defined.
23: And so we basically sought to
24: establish a threshold for what

p. 00344

00346

01: targeted media outreach."
02: Do you see that?
03: A. I do.
04: Q. That's the material that
05: includes the crisis playbook, correct?
06: MR. WEINSTEIN: Objection to
07: form.
08: THE WITNESS: Again, I'm not
09: exactly sure. The crisis playbook
10: was never -- it was a draft format
11: that was never released. It was
12: never published. It was -- we
13: didn't do anything with it. But
14: that was a product that APCO did
15: provide us in their initial
16: engagement.
17: BY MR. PIFKO:
18: Q. Okay. And you shared that
19: product with the HDA's members, correct?
20: MS. CHARLES: Objection to
21: form.
22: MR. WEINSTEIN: Objection to
23: form.
24: THE WITNESS: Again, I don't

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00347
01: recall. Our communications
02: department handled all that
03: interface with APCO.
04: BY MR. PIFKO:
05: Q. You wouldn't have any reason
06: to dispute that it was shared with
07: members?
08: MR. WEINSTEIN: Objection to
09: form.
10: MS. CHARLES: Objection to
11: form.
12: MS. ROLLINS: Objection to
13: form.
14: THE WITNESS: I can't say
15: one way or another.
16: BY MR. PIFKO:
17: Q. You would agree if it was
18: produced by one of the members in this
19: litigation, it must have been shared with
20: them obviously, right?
21: MR. WEINSTEIN: Objection to
22: form.
23: THE WITNESS: Yes.
24:

p. 00347

00349
01: danger. This manufacturer has reached
02: out to other manufacturers as well to
03: raise concerns."
04: Do you see that?
05: A. I do.
06: Q. Did I read that correctly?
07: A. You did.
08: Q. Okay. And then Kristen is
09: asking Linden to let her know thoughts on
10: the suggestions from these manufacturers,
11: agree?
12: A. Yes.
13: MR. WEINSTEIN: Objection to
14: form.
15: BY MR. PIFKO:
16: Q. Okay. And the suggested
17: changes from the manufacturer's attorney
18: are provided on the second page of this
19: document, correct?
20: A. Again, if this was attached
21: to the e-mail, then, yes, I would agree
22: that that includes -- was included in the
23: e-mail.
24: Q. Okay. And so, she

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00348
01: BY MR. PIFKO:
02: Q. I'm handing you what's been
03: marked Exhibit 36.
04: (Document marked for
05: identification as Exhibit
06: HDA-Kelly-36.)
07: BY MR. PIFKO:
08: Q. Take a moment to review that
09: and let me know when you're ready. For
10: the record, it's a single -- two-page
11: document, Bates-labeled HDA_MDL_000214864
12: through 4865.
13: A. Okay.
14: Q. This is an e-mail from
15: Kristen Freitas to Linden Barber.
16: Do you see that?
17: A. I do.
18: Q. And it says, "Manufacturer
19: issue with imminent danger definition."
20: Do you see that?
21: A. Yes.
22: Q. And it says, "We were
23: contacted by a manufacturer that has
24: concerns about the definition of imminent

p. 00348

00350
01: paraphrases comments from the
02: manufacturer's attorney in her e-mail to
03: Linden Barber. And she says, "My
04: suggested changes are" -- it basically
05: says that -- sorry, that, "The first
06: comment change could be ignored but the
07: second and third are, in my view,
08: critical to protect the interest of
09: virtually all DEA registrants, not just
10: manufacturers."
11: Do you see that?
12: A. Yes.
13: Q. Would you agree that at some
14: point the HDA also started working with
15: manufacturers and members of the Pain
16: Care Forum on the Marino/Blackburn bill?
17: MR. WEINSTEIN: Objection to
18: form.
19: MS. MACKAY: And foundation.
20: THE WITNESS: Again, I don't
21: know that we ever worked with the
22: Pain Care Forum on this bill. I
23: know that the manufacturers were
24: working with Senator Hatch's

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00351
01: office. And the concerns that
02: were expressing to Senator Hatch
03: we being expressed by Senator
04: Hatch's staff to us. And we were
05: asked to rectify those concerns
06: moving forward.
07: BY MR. PIFKO:
08: Q. The legislation from Senator
09: Hatch was the same?
10: MR. WEINSTEIN: Objection to
11: form.
12: THE WITNESS: The -- I'm
13: sorry?
14: BY MR. PIFKO:
15: Q. It's the same legislation,
16: you're dealing with Senator Hatch --
17: A. It was -- yes, it was -- it
18: was the senate version of the
19: Marino/Blackburn bill, Senate Bill 483,
20: or what became Senate Bill 483.
21: (Document marked for
22: identification as Exhibit
23: HDA-Kelly-37.)
24:

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00353
01: "Re-introduction of Ensuring Patient
02: Access and Effective Drug Enforcement
03: Act." That's the Marino/Blackburn bill,
04: correct?
05: A. Yes.
06: Q. Okay. And he then forwards
07: it to the members of the Pain Care Forum
08: on the first page.
09: Do you see that?
10: A. I do.
11: Q. And it's got attachments
12: that are summaries of the bill.
13: Do you see that on the
14: header?
15: A. I do.
16: Q. Okay. Oh, and she then
17: says, "Last year, we worked with a number
18: of you on a letter of support for
19: legislation introduced in the house and
20: senate establishing an enforcement
21: escalation procedure."
22: Do you see that?
23: A. Yes.
24: Q. I'm on the second page of

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00352
01: BY MR. PIFKO:
02: Q. I'm handing you what's
03: marked as Exhibit 37. It's a two-page
04: document, Bates-labeled HDA_MDL_000081283
05: through 284.
06: Take a minute to review it
07: and let me know when you're done.
08: A. Okay.
09: Q. Who is Jewelyn Cosgrove?
10: A. She works in the federal
11: government affairs department at HDA.
12: Q. Is she someone that reports
13: to you?
14: A. She reports to Kristen
15: Freitas.
16: Q. And she --
17: A. Ultimately under my
18: department, yes.
19: Q. Okay. So she writes to Burt
20: Rosen of Purdue and asks for him to share
21: this with the Pain Care Forum.
22: Do you see that?
23: A. Yes.
24: Q. And it's -- the subject is,

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00354
01: that.
02: A. Yes, yes, yes, yes.
03: Q. "And then for reference the
04: two bills were the Ensuring Patient
05: Access and Effective Drug Enforcement Act
06: in the House, Representatives Marino,
07: Blackburn, Welch, Chu; and the Regulatory
08: Transparency, Patient Access, and
09: Effective Drug Enforcement Act in the
10: Senate from Senators Hatch and
11: Whitehouse."
12: Do you see that?
13: A. Yes.
14: Q. And then later on the
15: bottom, "With the process moving quickly,
16: we would like to ask those of you who
17: signed the senate letter of support from
18: patient groups last year to consider
19: supporting the House legislation."
20: Do you see that?
21: A. I do.
22: Q. I'm handing you what's
23: marked as Exhibit 38.
24: (Document marked for

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00355
01: identification as Exhibit
02: HDA-Kelly-38.)
03: BY MR. PIFKO:
04: Q. Take a moment to review
05: Exhibit 38. And let me know when you're
06: done.
07: For the record, Exhibit 38
08: is a four-page document Bates-labeled
09: HDA_MDL_000081651 through 81654.
10: A. Okay.
11: Q. This just confirms in
12: response to Jewelyn's request that the
13: Pain Care Forum support the bill. Burt
14: Rosen from Purdue then sends her back the
15: letter signed and -- with their
16: endorsement. Agree?
17: UNIDENTIFIED LAWYER:
18: Objection. Form.
19: MR. WEINSTEIN: Objection to
20: form.
21: MS. MACKAY: Objection to
22: form.
23: THE WITNESS: Yes.
24: BY MR. PIFKO:

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00357
01: Mr. Gray provided for the House of
02: Representatives energy and commerce
03: committee subcommittee on health --
04: A. It --
05: Q. -- from April 7, 2014?
06: A. It is.
07: Q. These are statements that he
08: made before that committee?
09: A. This is the written
10: statement. I don't know how much it
11: deviated from the oral statement.
12: Q. Okay. And you participated
13: in -- in writing this?
14: A. I helped to prepare it, yes.
15: Q. Okay. Anyone else?
16: A. The whole government affairs
17: team. Probably our communication team as
18: well.
19: Q. And in this he's discussing,
20: the Marino/Blackburn bill, correct?
21: A. Yes.
22: Q. Second sentence, "Thank you
23: for the opportunity to discuss with the
24: subcommittee important legislation

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00356
01: Q. I'm handing you what's
02: marked as Exhibit 39.
03: (Document marked for
04: identification as Exhibit
05: HDA-Kelly-39.)
06: BY MR. PIFKO:
07: Q. This document is not
08: Bates-labeled. We printed it from HDA's
09: website. Take a moment to review it.
10: For the record, it's a
11: document that is identified on the first
12: page as "Statement from John Gray,
13: President and CEO, Healthcare
14: Distribution Management Association For
15: the U.S. House of Representatives Energy
16: and Commerce Committee, Subcommittee on
17: Health," dated April 7, 2014. It's a
18: five-page document.
19: Have you seen this before?
20: A. I have.
21: Q. Did you assist in preparing
22: this testimony?
23: A. I did.
24: Q. And this is testimony that

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00358
01: introduced by Representatives Blackburn
02: and Marino, the Ensuring Patient Access
03: and Effective Drug Enforcement Act of
04: 2014," correct?
05: A. Yes.
06: Q. Then the next paragraph,
07: second sentence, he says, "Our industry's
08: primary mission is to operate the safest
09: and most secure and efficient supply
10: chain in the world."
11: Agree with that statement?
12: A. I do.
13: Q. "As part of this mission,
14: the pharmaceutical industry is committed
15: to addressing the serious national
16: epidemic of prescription drug abuse."
17: Do you see that?
18: A. I do.
19: MR. WEINSTEIN: You missed
20: the word "distribution" in there,
21: you missed.
22: MR. PIFKO: Sorry. I'll
23: read it again for the record.
24: BY MR. PIFKO:

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00359

01: Q. To be clear, so Mr. Gray
02: testified before this committee and said
03: that "the pharmaceutical distribution
04: industry is committed to addressing the
05: serious national epidemic of prescription
06: drug abuse," correct?
07: A. Yes.
08: Q. Next paragraph. Mr. Gray
09: also told the committee, "HDMA's members
10: are committed to working proactively with
11: DEA," correct?
12: A. Yes.
13: Q. Page 2 of the testimony. He
14: says, "This is one of the reasons" --
15: second full paragraph. "This is one of
16: the reasons why HDMA supports HR 4069."
17: That's the Marino/Blackburn
18: bill, correct?
19: A. Yes.
20: Q. He says this -- he told the
21: committee, "This legislation is a timely
22: and thoughtful approach to addressing the
23: prescription drug epidemic," correct?
24: A. Yes.

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00361

01: dated -- or dated March 24, 2014.
02: Bates-labeled MCKMDL00651560 to 651563.
03: Take a moment to review that
04: and let me know when you're done.
05: A. Okay.
06: Q. So, on the first page
07: there's an e-mail here from you to Ann
08: Berkley. Who is Ann Berkley?
09: A. Ann Berkey was --
10: Q. Sorry.
11: A. -- at the time the head of
12: the government affairs operation at
13: McKesson.
14: Q. Okay. And you also reach
15: out to Connie Woodburn and Rita Norton?
16: A. Right. The only -- they are
17: the only company government affairs
18: representatives from any of our member
19: companies.
20: Q. Okay. So you are reaching
21: out to McKesson, Cardinal, and
22: AmerisourceBergen, correct?
23: A. Right.
24: Q. And at the bottom you say,

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00360

01: Q. And he said, "We will
02: believe it will foster greater
03: collaboration, communication and
04: transparency between" -- "between
05: industry stakeholders and regulators,
06: especially the DEA," correct?
07: A. Correct.
08: Q. And then in the next
09: paragraph he talks about establishing a
10: collaborative working relationship with
11: the DEA.
12: Do you see that?
13: A. Yes.
14: Q. And he provided that
15: testimony to the subcommittee as well,
16: correct?
17: A. Yes.
18: (Document marked for
19: identification as Exhibit
20: HDA-Kelly-40.)
21: BY MR. PIFKO:
22: Q. I'm handing you what's
23: marked as Exhibit 40. It's an e-mail
24: from you to Ann Berkey of McKesson,

p. 00360

00362

01: "It looks like we have some challenges
02: finding a time that worked for everyone.
03: Can we possibly do a quick call for
04: today? If not, I can fill everyone in
05: via e-mail regarding a discussion the
06: executive committee had last week on the
07: topic of drug abuse diversion
08: specifically with regard to the
09: Marino/Blackburn legislation."
10: Do you see that?
11: A. I do.
12: Q. Okay. So you sought to
13: update them with -- with respect to a
14: discussion the executive committee had on
15: the Marino/Blackburn legislation,
16: correct?
17: A. Yes, yes, that's what this
18: indicates.
19: Q. Okay. And then in the
20: e-mail on the top, Ann, you write to Ann.
21: She apparently said she was on a plane,
22: and then you write to her and say, about
23: halfway down that e-mail, "John sent a
24: memo, attached."

p. 00362

00363
01: Do you see that?
02: A. Yes.
03: Q. "To executive committee
04: members on Friday."
05: Do you see that?
06: A. I do.
07: Q. "Regarding next steps on the
08: Marino/Blackburn legislation."
09: Do you see that?
10: A. Yes.
11: Q. And then you've got the --
12: the memos attached here to this e-mail?
13: A. Mm-hmm.
14: Q. It's entitled, "Status of
15: HR 4069."
16: Yes?
17: A. Yes.
18: Q. Who put this memo together?
19: John Gray?
20: A. It was probably prepared by
21: the government affairs department.
22: Q. Okay. Did you have an
23: involvement in putting this together?
24: A. I don't know that I'd wrote

p. 00363

00365
01: this legislation would tie the agency's
02: hand?
03: MR. WEINSTEIN: Objection to
04: form. Foundation.
05: THE WITNESS: Yeah, this
06: version -- again, this was two
07: years before the bill was passed,
08: and it was changed multiple times
09: afterwards with their input and
10: feedback.
11: So initial versions were,
12: yes, opposed by the agency.
13: BY MR. PIFKO:
14: Q. And then it says,
15: "Essentially, the DEA is categorically
16: opposed to the provisions in the
17: legislation to mandate definitions of
18: imminent danger and consistent with
19: public health and safety."
20: Do you see that?
21: A. I do.
22: Q. It was your understanding
23: that DEA was categorically opposed to
24: those provisions?

p. 00365

00364
01: it. But I probably saw before it was
02: submitted to the executive committee.
03: Q. Okay. I want to turn your
04: attention to the second page of the memo,
05: third page of Exhibit 40. There's a
06: heading "DEA."
07: Do you see that?
08: A. I do.
09: Q. "In conversations with
10: numerous HDMA member companies and select
11: Hill staff, as well as Al Santos,
12: recently retired from DEA office of
13: diversion control, it is our
14: understanding that DEA is very concerned
15: with this legislation 'tying the agencies
16: hands' to actively and aggressively
17: address diversion and compliance with the
18: CSA."
19: Do you see that?
20: A. I do.
21: Q. Did I read that correctly?
22: A. You read it verbatim.
23: Q. Okay. It was HDA and its
24: members' understanding that DEA felt that

p. 00364

00366
01: MR. WEINSTEIN: Objection to
02: form.
03: THE WITNESS: They were --
04: at the time they were concerned
05: that providing any definition of
06: those terms would somehow require
07: them to satisfy criteria that they
08: didn't have to meet at that point
09: in time.
10: BY MR. PIFKO:
11: Q. And then it says, "They were
12: also categorically opposed to
13: implementing corrective action plans as
14: well."
15: Correct?
16: A. Yes.
17: Q. "And they were categorically
18: opposed to force the agency to
19: participate in a stakeholder working
20: group."
21: Correct?
22: MR. WEINSTEIN: Objection to
23: form.
24: THE WITNESS: That's what it

p. 00366
Page 96

00367
01: says, yes.
02: BY MR. PIFKO:
03: Q. Was that your understanding
04: that they were -- they were categorically
05: opposed to that?
06: A. Again, I --
07: MR. WEINSTEIN: Objection to
08: form.
09: THE WITNESS: I don't know
10: what -- what categorically they
11: were more opposed to than not.
12: But they were opposed to
13: essentially most of that --
14: BY MR. PIFKO:
15: Q. Those future --
16: A. -- most of those issues,
17: yes.
18: Q. And the last page of the
19: memo there's some other bullet points.
20: One of them is -- the top one on the last
21: page. It says, "DEA is adamantly opposed
22: to this legislation and has made their
23: position known to Hill staff as well as
24: to some industry representatives."

p. 00367

00369
01: final version of that legislation.
02: MR. WEINSTEIN: We've been
03: going about an hour.
04: MR. PIFKO: We'll take a
05: break in about two seconds.
06: BY MR. PIFKO:
07: Q. I want to turn your
08: attention back to Exhibit 31 to Page 11
09: and 12. I want to direct you to language
10: on Page 12, but 11 tells you that this
11: was a discussion that occurred at the
12: September 28, 2015, board of directors
13: meeting. Turn to Page 12. Tell me when
14: you're ready.
15: A. Okay.
16: Q. During this September 28,
17: 2015, board of directors meeting,
18: "President Gray noted HDMA executive
19: committee had discussed and agreed to
20: prioritize objectives on prescription
21: drug abuse in the following order: Item
22: Number 1, exhaust all efforts to secure
23: passage of S.483."
24: Do you see that?

p. 00369

00368
01: Do you see that?
02: A. Yes.
03: Q. It was your understanding
04: that they were adamantly opposed to
05: legislation at that time?
06: A. To that version of the bill
07: in 2014, which is two years before the
08: final bill was passed, yes.
09: Q. Did the final bill have the
10: definition of imminent danger?
11: A. It did.
12: Q. Did it have the corrective
13: action plan?
14: A. It did.
15: Q. Did it mandate the DEA to
16: participate in a stakeholder working
17: group?
18: A. It did.
19: Q. Did it add the "consistent
20: with public health and safety" language?
21: A. I don't know if the specific
22: language was in there. I'm happy to look
23: at the final version of the bill and tell
24: you, yes. And DEA did not oppose the

p. 00368

00370
01: A. On -- which page are you on?
02: Q. 12.
03: A. Oh, yes. Okay, I see it.
04: Q. Did I read that correctly?
05: A. "Exhaust all efforts to
06: secure passage of S.483." Yes.
07: Q. So S.483 is the final
08: version that got passed?
09: A. It was, yes, the bill that
10: got passed by the senate and approved
11: unanimously both -- in both chambers and
12: signed by President Obama.
13: MR. PIFKO: Okay. We can
14: take a break.
15: THE VIDEOGRAPHER: The time
16: is 3:51 p.m. We are going off the
17: record.
18: (Short break.)
19: THE VIDEOGRAPHER: The time
20: is 4:11 p.m. We are back on the
21: record.
22: (Document marked for
23: identification as Exhibit
24: HDA-Kelly-41.)

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00371
01: BY MR. PIFKO:
02: Q. I'm handing you what's been
03: marked Exhibit 41.
04: For the record it's a series
05: of e-mails, the recent one dated Monday,
06: May 1st, 2017, from Matt DiLoreto to Beth
07: Mitchell. Bates-labeled
08: HDA_MDL_000214979 through 214982.
09: On the first page of this
10: document, Beth Mitchell from
11: AmerisourceBergen writes to Matt DiLoreto
12: on Monday, May 1st, 2017. She says, "Hi,
13: Matt. Have you been able to find
14: anything? Any state bills or approaches
15: we have ever been able to say yes, we
16: support this as an effort to address
17: opioid abuse?"
18: Do you see that?
19: A. I do.
20: Q. Matt writes back, and says,
21: "Sorry for the delay on this project, but
22: I was really hoping to find something."
23: Do you see that?
24: A. Yes.

p. 00371

00373
01: got the most pressure and allocate
02: resources there.
03: But at the federal level and
04: with the media, we've done a lot of work
05: with coalitions. We did our practical
06: solutions suggestions. We worked with
07: various state organizations, NADDI,
08: National Association of Boards of
09: Pharmacy, National Community Pharmacists
10: Association to support initiatives to
11: address prescription drug abuse and
12: diversion with them.
13: Whether or not we were able
14: to support a particular bill in a state,
15: that's going to be probably a little bit
16: more difficult given the resource
17: challenges we have. But as far as
18: activities and publicly supporting opioid
19: prevention measures, we absolutely have
20: been very involved, very engaged on that
21: issue.
22: Q. Okay. But with respect to
23: legislation or bills, is it a true
24: statement that HDA has never publicly

p. 00373

00372
01: Q. And then at the bottom of
02: his e-mail there on the first page, he
03: says, "Bottom line is I talked with both
04: Patrick and Liz, and they cannot recall
05: any time that we openly and publicly
06: supported an opioid abuse prevention
07: measure."
08: Do you see that?
09: A. I do.
10: Q. Is that a correct statement?
11: A. That's not a correct
12: statement.
13: Q. What opioid abuse prevention
14: measures has HDA supported?
15: A. A significant number of
16: provisions across the -- I mean, at the
17: state level, it's harder because we're
18: much more -- we have a smaller group, and
19: it's difficult to be kind of proactive at
20: the state level. We have to be more
21: reactive than not. So allocating
22: resources at the state level can be a
23: challenge.
24: So we tend to go where we've

p. 00372

00374
01: supported an opioid abuse prevention
02: measure?
03: MR. WEINSTEIN: Objection to
04: form.
05: THE WITNESS: I can't --
06: again, one doesn't immediately
07: jump to mind. That's not to say
08: that there are bills out there
09: that had passed that just maybe we
10: didn't even think were opioid
11: abuse prevention measures. But
12: I -- I can't -- again, don't --
13: don't have one that I can
14: immediately point to.
15: I can -- you know what, let
16: me clarify that. There are bills
17: with regard to suspicious order
18: monitoring. We've been requested
19: to have -- support state
20: regulatory authorities access to
21: suspicious order monitoring and
22: ARCOS data, that we're happy to
23: work with in the State of
24: Virginia, State of West Virginia,

p. 00374

00375

01: State of Tennessee, all requested
02: that we provide opioid
03: distribution information to them.
04: We complied and said as long as,
05: you know, it's duplicative of what
06: we're sending to DEA, we're happy
07: to do that.
08: BY MR. PIFKO:
09: Q. When you say opioid
10: distribution information, what do you
11: mean?
12: A. ARCOS data.
13: Q. Okay.
14: A. ARCOS data and suspicious
15: order monitoring reports.
16: Q. Okay. But that's not any
17: legislation or bills, correct?
18: A. It's not.
19: Q. I'm handing you what's
20: marked as Exhibit 42.
21: (Document marked for
22: identification as Exhibit
23: HDA-Kelly-42.)
24: BY MR. PIFKO:

p. 00375

00376

01: Q. It's another e-mails with
02: agenda and summary of meetings from Anita
03: Ducca back in 2008. Bates-labeled
04: CAH_MDL2804_01364288 through 300.
05: This is a lengthy document,
06: but I just want to ask you about one
07: provision in here.
08: A. Is there a specific
09: provision?
10: Q. Yeah, I was waiting for you
11: to tell me you were ready.
12: A. Okay. I'm ready.
13: Q. So the -- on the first page
14: it's an e-mail from Anita Ducca, another
15: one of her reminders about conference
16: calls. And she's attaching a summary of
17: a regulatory affairs meeting that
18: occurred on July 17, 2008. It's five
19: pages in.
20: Do you see that?
21: A. Yes.
22: Q. Okay. Do you have any
23: reason to dispute that these are accurate
24: notes of the meeting?

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00377

01: MR. WEINSTEIN: Objection to
02: form. Foundation.
03: THE WITNESS: I do not. I
04: can't say for certain. I was not
05: HDA at the time. But I will take
06: it at face value that they were
07: accurate that they were sent out
08: by Anita.
09: BY MR. PIFKO:
10: Q. You understand that you --
11: one of your designations here as a
12: 30(b)(6) witness for -- for HDA is
13: committee meetings --
14: A. Yes.
15: Q. -- concerning opioids and
16: the substance of those meetings, correct?
17: MR. WEINSTEIN: Objection to
18: form.
19: THE WITNESS: I do, yes.
20: BY MR. PIFKO:
21: Q. Okay. And so you don't have
22: any reason to dispute that these are
23: accurate notes?
24: MR. WEINSTEIN: Objection to

p. 00377

00378

01: form.
02: THE WITNESS: I have no
03: reason to dispute that these are
04: accurate notes.
05: BY MR. PIFKO:
06: Q. Okay. So I want to direct
07: your attention to Page 3 of the notes,
08: which is CAH_MDL2804_01364294. Tell me
09: when you're there.
10: A. I see it.
11: Q. Okay. There's a section
12: here, it says, "Proposed rule on quotas."
13: Do you see that?
14: A. Yeah.
15: Q. Okay. Does DEA participate
16: in these meetings from time to time?
17: MR. WEINSTEIN: Objection to
18: form.
19: THE WITNESS: Participate in
20: what meetings?
21: BY MR. PIFKO:
22: Q. The regulatory affairs
23: meetings.
24: A. They are invited guests in

p. 00378

00379

01: some instances.
02: Q. Okay. On the first page of
03: the notes it says, "Four staff members of
04: the DEA join the meeting at approximately
05: 9:15. Mark Caverly explained that since
06: it was an election year, DEA expected a
07: slowdown in new initiatives, and the
08: Office of Management and Budget has told
09: DEA staff not to submit new major
10: rulemakings."
11: Do you see that?
12: A. No. What page are you?
13: Q. First page of the notes.
14: Fifth page of the document. 1364292.
15: A. Okay.
16: Q. Do you see that?
17: A. Four members, yes, okay.
18: I'm -- I'm with you.
19: Q. So the four members from DEA
20: joined the meeting, correct?
21: A. Correct.
22: Q. And then the -- the members
23: of the regulatory affairs committee would
24: have participated as well, correct?

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00381

01: A. Yes.
02: Q. Okay. So going -- sorry,
03: going back to the third page of the
04: notes. 1364294. Let me know when you're
05: there.
06: A. I'm there.
07: Q. It says, "Proposed rule on
08: quotas for Schedule I and Schedule II
09: substances. DEA discussed the reduction
10: in illicit internet purchases and its
11: impact on decisions on manufacturing
12: quota sizes. We pointed out the
13: incongruity of DEA's increases in quota
14: sizes and the expectation that
15: distributors will cut back on
16: distribution."
17: Do you see that?
18: A. I do.
19: Q. Do you have any reason to
20: dispute that this was discussed at the
21: meeting?
22: A. I do not.
23: Q. So to your knowledge, this
24: was discussed at the meeting?

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00380

01: A. I believe so, yes.
02: Q. It says, "The agenda and
03: list of attendees and guests are
04: attached"?
05: A. Okay.
06: Q. Do you see that, it says
07: that on the first page?
08: A. Yes.
09: Q. And then we see that HDA
10: members present, if you go to Page 5 of
11: the notes, 1364296?
12: A. I do.
13: Q. Okay. It's got Steve
14: Reardon from Cardinal, Mark Hartman from
15: Cardinal, Gary Hilliard from McKesson,
16: Steve Mays from AmerisourceBergen.
17: Do you see that?
18: A. And Mike Shoneff from
19: Valley, and Roger Peters, and Brad Pine
20: and Mike DeBello and Sergio Tejada.
21: Q. Okay. And then it's got the
22: DEA staff that attended as well?
23: A. Yes.
24: Q. And HDMA staff, correct?

p. 00380

00382

01: MR. WEINSTEIN: Objection to
02: form.
03: THE WITNESS: To my
04: knowledge it was discussed at the
05: meeting.
06: (Document marked for
07: identification as Exhibit
08: HDA-Kelly-43.)
09: BY MR. PIFKO:
10: Q. I'm handing you what's
11: marked as Exhibit 43. It is a three-page
12: document, Bates-labeled HDA_MDL_000088099
13: through 88101.
14: Take a minute to review this
15: and let me know when you're done.
16: A. Okay.
17: Q. You are part of the e-mail
18: at the bottom here from John Parker to a
19: bunch of people including you, do you see
20: that, dated February 8, 2012?
21: A. Yes.
22: Q. It says, "New DEA
23: talking" -- "TPs," talking points,
24: correct?

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00383
01: A. Yes.
02: Q. "Attached are the revised
03: DEA talking points. I essentially kept
04: one of Cardinal's three bullets with a
05: few modifications."
06: Did I read that correctly?
07: A. You did.
08: Q. So HDA worked with members
09: of the executive committee to draft
10: talking points concerning the District
11: Court's TRO against the DEA's suspension
12: order of Cardinal Health Lakeland
13: distribution center, correct?
14: MS. ROLLINS: Objection to
15: form.
16: MS. WICHT: Objection.
17: THE WITNESS: That's what
18: the first bullet point says, yes.
19: BY MR. PIFKO:
20: Q. And the executive committee
21: worked to draft these; is that correct?
22: MR. WEINSTEIN: Objection to
23: form.
24: THE WITNESS: Again, I don't

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00385
01: of --
02: A. That is my understanding.
03: Q. -- what happened?
04: A. Again, I don't recall this
05: particular document. But I will not
06: dispute what the e-mail says.
07: Q. Do you know if
08: AmerisourceBergen ultimately approved the
09: talking points?
10: A. I do not.
11: Q. What were these talking
12: points to be used for?
13: MR. WEINSTEIN: Objection to
14: form.
15: THE WITNESS: Again, I don't
16: know specifically what these were
17: developed to address. Possibly
18: media coverage of the case
19: referenced in the first bullet
20: point.
21: BY MR. PIFKO:
22: Q. In the first bullet point,
23: it says, "HDMA is pleased that the
24: District Court granted the TRO against

p. 00385

00384
01: think the executive committee
02: drafted them. I think they were
03: probably shared with the executive
04: committee. And if they had
05: comments or provided feedback,
06: that was incorporated.
07: BY MR. PIFKO:
08: Q. Okay. Well, at the top of
09: this e-mail, John Gray writes to David
10: Neu from AmerisourceBergen, and says,
11: "For our 12:30 call, attached is the
12: latest version based on input from the
13: rest of the executive committee."
14: Do you see that?
15: A. Yes.
16: Q. So this has had input from
17: everybody but AmerisourceBergen at this
18: point, correct?
19: MR. WEINSTEIN: Objection to
20: form.
21: THE WITNESS: That's what it
22: says, yes.
23: BY MR. PIFKO:
24: Q. Is that your understanding

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00386
01: the DEA," correct?
02: A. That's what it says, yes.
03: Q. And, "It allows Cardinal
04: Health to resume shipments of controlled
05: substances," correct? Second bullet
06: point says that?
07: A. Yes. That's what it says.
08: Q. Was this put on HDA's
09: website?
10: A. I do not know. It says at
11: the top, this is for internal use only,
12: do not distribute. So I would imagine it
13: did not make it to --
14: Q. Okay. Maybe some other
15: version? In your experience would
16: something like this be put on their -- on
17: the website?
18: MR. WEINSTEIN: Objection to
19: form.
20: THE WITNESS: Again,
21: specific talking points wouldn't
22: be put on the website. It would
23: be more, you know, kind of
24: policies, papers or statements or

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00387

01: comments that were submitted.
02: Talking points are generally
03: internal documents for purposes of
04: discussions either on the Hill or
05: with the media.
06: BY MR. PIFKO:
07: Q. Okay. So these could have
08: been used by your staff in talking to
09: members of the Hill?
10: A. They could have been.
11: MS. ROLLINS: Objection to
12: form.
13: BY MR. PIFKO:
14: Q. To your knowledge were they
15: used for that?
16: A. I -- not to my knowledge. I
17: don't know. I can't say for certain one
18: way or another.
19: Q. So sitting here today you
20: don't have any recollection of how these
21: were used?
22: A. Again, it's 2012. I don't
23: recall.
24: Q. I'll have you look back at

p. 00387

00389

01: part of the entry, it says, "EC" --
02: that's executive committee, correct?
03: A. That's correct.
04: Q. -- "asked OFW" -- that's
05: Olsson Frank, the outside counsel,
06: correct?
07: A. Correct.
08: Q. -- "to prepare a draft
09: amicus brief in the Cardinal case."
10: Correct?
11: A. Correct.
12: Q. So it's your understanding
13: that the executive committee asked HDA's
14: outside counsel to prepare an amicus
15: brief for the Cardinal case in
16: February 2012, correct?
17: A. That's correct.
18: Q. I'm handing you what's
19: marked Exhibit 44.
20: (Document marked for
21: identification as Exhibit
22: HDA-Kelly-44.)
23: BY MR. PIFKO:
24: Q. For the record it's an

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00388

01: Exhibit 31. It looks like this.
02: A. Yes.
03: Q. The first entry on February
04: 16, 2012 --
05: (Brief interruption.)
06: THE VIDEOGRAPHER: Off the
07: record. 4:29 p.m.
08: (Brief pause.)
09: THE VIDEOGRAPHER: The time
10: is 4:33 p.m. We are back on the
11: record.
12: BY MR. PIFKO:
13: Q. All right. So we're looking
14: at Exhibit 31 at the first entry dated
15: February 16, 2012.
16: Do you see that?
17: A. Yes.
18: Q. So this is a summary of the
19: portions of the executive committee,
20: correct?
21: A. Yes.
22: Q. Of the executive committee
23: meeting. And so it says that HDMA met
24: with DEA staff. And then at the second

p. 00388

00390

01: e-mail from John Gray. At the top
02: there's some other e-mails. The top
03: e-mail is dated Thursday, February 23rd,
04: 2012. And the subject is, "Draft Amicus
05: Brief, Cardinal Health v. Holder."
06: It's Bates-labeled
07: HDA_MDL_000215212 through 215233.
08: Take a minute to review that
09: and let me know when you're done.
10: A. Okay.
11: Q. So at the bottom of this
12: e-mail, David Durkin is e-mailing to
13: Richard Frank a revised draft of the
14: brief, agree?
15: A. Yes.
16: Q. Then, Richard Frank forwards
17: it. Richard Frank is an attorney at
18: Olsson Frank, correct?
19: A. Correct.
20: Q. Outside counsel for HDA,
21: correct?
22: A. Correct.
23: Q. Okay. He forwards the draft
24: amicus brief to John Gray and you and

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00391
01: others in HDA, correct?
02: A. Correct.
03: Q. And he writes, "HDMA
04: colleagues, attached is the draft amicus
05: brief for your consideration. The
06: executive committee asked that this be
07: sent to them for approval or objection
08: prior to filing. We should also run it
09: by Cardinal's counsel."
10: Did I read that correctly?
11: A. You did.
12: Q. Okay. Do you recall
13: receiving that e-mail?
14: A. I'm obviously here on the
15: addressees. Yes.
16: Q. Okay. And then at the top
17: of this e-mail here, John Gray forwards
18: it to David Moody, and David Neu from
19: AmerisourceBergen correct?
20: A. Correct. David Moody was
21: North Carolina Mutual and the chairman of
22: the organization.
23: Q. Okay. Is it your
24: understanding that John Gray also

p. 00391

00393
01: MR. WEINSTEIN: Objection to
02: form.
03: THE WITNESS: I do not
04: recall specific concerns about the
05: aggressive Section 3.
06: BY MR. PIFKO:
07: Q. John Gray never shared that
08: information with you?
09: MR. WEINSTEIN: Objection to
10: form.
11: THE WITNESS: Again, I don't
12: recall. They may have shared that
13: information, there may have been
14: discussion about it. I just don't
15: recall.
16: BY MR. PIFKO:
17: Q. I'm handing you what's been
18: marked Exhibit 45.
19: (Document marked for
20: identification as Exhibit
21: HDA-Kelly-45.)
22: BY MR. PIFKO:
23: Q. Series of e-mails concerning
24: the same subject to Cardinal v. Holder

p. 00393

00392
01: forwarded the draft to the other members
02: of the executive committee as well?
03: MR. WEINSTEIN: Objection to
04: form. Foundation.
05: THE WITNESS: Again, I would
06: deduce that based on the executive
07: committee request. But this is
08: sent to the chairman and vice
09: chairman.
10: BY MR. PIFKO:
11: Q. So he sends it to them and
12: says, "Attached is a draft amicus brief
13: that HDMA could file on behalf of our
14: membership in support of the Cardinal
15: case next week. I think it's an
16: excellent recitation of our issues with
17: DEA. However, I fear it may be too
18: aggressive in Section 3 at this point in
19: time."
20: Do you see that?
21: A. Yes, I can read that.
22: Q. Do you recall any
23: discussions about what specifically was
24: too aggressive in Section 3?

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00394
01: amicus brief. It's Bates-labeled
02: HDA_MDL_000215970 through 215973.
03: Take a moment to review this
04: and let me know when you're done.
05: A. Okay.
06: Q. You ready?
07: So on the last page of this
08: document, which is the earliest of the
09: e-mail thread, David Durkin, he's outside
10: counsel for HDA, correct?
11: A. Correct.
12: Q. He is the one who authored
13: the amicus brief for the Cardinal v.
14: Holder case, correct?
15: A. Correct.
16: Q. He's writing to Doug
17: Farquhar -- am I saying that right?
18: A. Yes.
19: Q. Doug -- do you know who Doug
20: Farquhar is?
21: A. I believe he is an attorney
22: at Hyman Phelps.
23: Q. Okay. And he was outside
24: counsel for Cardinal Health in the

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00395
01: underlying litigation, correct?
02: A. I -- I think so, yes. I
03: can't recall specifically.
04: Q. So David Durkin is asking
05: him for thoughts on how to handle the
06: judge in that case on the first page.
07: Do you see that?
08: MR. WEINSTEIN: Objection to
09: form.
10: MS. WICHT: Objection to
11: form.
12: BY MR. PIFKO:
13: Q. Do you agree with that?
14: MR. WEINSTEIN: Objection to
15: form.
16: THE WITNESS: I agree that
17: there is a question to Doug about
18: the handling of the case, yes.
19: BY MR. PIFKO:
20: Q. And handling of how the
21: judge is handling the matter?
22: A. Yes.
23: Q. And anything he -- he's
24: asking anything you want me to be aware

p. 00395

00397
01: A. I agree.
02: Q. Linden Barber was inhouse
03: counsel for Cardinal Health at this
04: point?
05: MS. WICHT: Objection to
06: form. Foundation.
07: THE WITNESS: I think Linden
08: at this time was with Quarles &
09: Brady.
10: BY MR. PIFKO:
11: Q. He was outside counsel for
12: Cardinal at this point, correct -- is
13: that correct?
14: A. Again, I don't know what his
15: specific role, or relationship was. But
16: I think he was, yes, at one point in
17: time. I don't know when that -- when
18: that engagement began.
19: Q. Okay. And then you were
20: aware that Cardinal's outside counsel had
21: provided comments on this brief, because
22: then David Durkin forwards this to you
23: with the subject Cardinal's counsel's
24: comments on amicus brief on Monday,

p. 00397

00396
01: of with regard to how Judge Walton is
02: handling this matter?
03: A. That's what it says, yes.
04: Q. Okay. And Doug Farquhar
05: writes back. And then there is some
06: subsequent discussions.
07: And then on February 24,
08: 2012, Doug writes to David Durkin copying
09: Linden Barber.
10: Do you see that?
11: A. Yes.
12: Q. Starts on the first page of
13: the document?
14: A. Yes, yes, yes, yes.
15: Q. And he says, "David, Linden
16: Barber and I have reviewed the amicus
17: brief and think it's really quite good.
18: Cardinal Health does, in fact, authorize
19: you to represent that we consent to your
20: motion for leave to file. We make the
21: following suggestions," and then there's
22: a page of suggestions, and then it goes
23: on to the next page with the suggestions.
24: Agree?

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00398
01: February 27, 2012, correct?
02: A. Yes.
03: Q. And we -- you know, but I
04: don't know what's there, because it's
05: redacted, correct?
06: A. I don't recall either, but I
07: see that my name was on the e-mail.
08: (Document marked for
09: identification as Exhibit
10: HDA-Kelly-46.)
11: BY MR. PIFKO:
12: Q. I'm handing you what's
13: marked as Exhibit 46. For the record,
14: it's a three-page document Bates-labeled
15: HDA_MDL_000216300 through 216302.
16: The subject is the HDMA
17: amicus brief, Cardinal v. Holder, DC
18: Circuit. The most recent e-mail is dated
19: March 5, 2012.
20: A. Okay.
21: Q. The HDA couldn't have filed
22: this brief unless they got approval from
23: all the members of the executive
24: committee, correct?

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00399

01: MR. WEINSTEIN: Objection to
02: form.
03: THE WITNESS: That's usually
04: the process. They try to get
05: consensus approval, yes.
06: BY MR. PIFKO:
07: Q. That's the process here as
08: well?
09: A. I believe so, yes.
10: Q. John Gray writes to the
11: members of the executive committee on
12: March 4, 2012. Do you see that, on the
13: bottom of the first page?
14: A. Yes.
15: Q. I have it right that he's
16: writing to the members of the executive
17: committee?
18: A. At the time, yes.
19: Q. Okay. And he's -- and that
20: includes AmerisourceBergen, McKesson, and
21: Cardinal Health, correct?
22: A. And HD Smith and Dakota Drug
23: and Smith Drug and North Carolina Mutual.
24: Q. Okay. And he says, "I

p. 00399

00401

01: MS. CHARLES: Form.
02: THE WITNESS: If it's stated
03: here that they were given an
04: opportunity to review the brief,
05: yes.
06: BY MR. PIFKO:
07: Q. And John Gray further
08: states, "I agree with HDMA counsel that
09: this is the best time to file such a
10: brief, to let the appellate court
11: understand the extent of our industry's
12: concerns and frustrations in trying to
13: work with the DEA on suspicious order
14: monitoring."
15: Did I read that correctly?
16: A. Suspicious ordering
17: monitoring. But, yes.
18: Q. "This may be the last chance
19: to address these issues before an
20: appellate bench in this matter. A
21: favorable decision will establish a
22: useful judicial precedent for all HDMA
23: members to rely upon if necessary."
24: Do you see that?

p. 00401

00400

01: apologize for" -- "apologize for
02: interrupting your weekend. HDMA outside
03: counsel was informed today that the U.S.
04: Court of Appeals in Washington agreed
05: late Friday to stay the district court's
06: ruling last Wednesday lifting the TRO on
07: the DEA's immediate suspension order
08: against Cardinal Health.
09: "As such, HDMA counsel is
10: recommending that HDMA now file the
11: amicus brief prepared after our recent
12: executive committee to set forth HDMA's
13: overall industry concern."
14: Do you see that?
15: A. I do.
16: Q. Okay. Do I have that
17: correct?
18: A. Yes.
19: Q. "This draft brief was
20: reviewed by most of you early last week."
21: Do you agree that the
22: members of the executive committee were
23: given the opportunity to review the
24: brief?

p. 00400

00402

01: A. Yes.
02: Q. Did you have an
03: understanding about what the significance
04: of the rulings were in this case?
05: MR. WEINSTEIN: Objection to
06: form.
07: THE WITNESS: I understood
08: the process that kind of launched
09: the -- the need for filing of the
10: amicus, yes.
11: BY MR. PIFKO:
12: Q. And what -- what was that?
13: A. Just the process that DEA
14: utilized to issue their suspension order,
15: was what I think we -- we were concerned
16: was vague and, you know, I think
17: illustrated the concerns that the -- the
18: entire industry had with the lack of
19: clarity that the industry had with regard
20: to DEA expectations and their enforcement
21: authorities.
22: Q. Do you know what the outcome
23: of the matter was?
24: MR. WEINSTEIN: Objection to

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00403
01: scope.
02: THE WITNESS: In the
03: Cardinal v. Holder case?
04: BY MR. PIFKO:
05: Q. Yeah.
06: A. I don't recall initially.
07: Q. Are you aware that Cardinal
08: Health eventually admitted wrongdoing?
09: MS. WICHT: Objection to
10: form.
11: MR. WEINSTEIN: Objection to
12: scope.
13: THE WITNESS: Again, I --
14: there was resolution of the case.
15: I don't know what the exact
16: details of the resolution were.
17: BY MR. PIFKO:
18: Q. Did anyone tell you that
19: Cardinal Health had admitted wrongdoing?
20: A. I think --
21: MR. WEINSTEIN: Objection to
22: scope.
23: MS. WICHT: Objection to
24: form.

p. 00403

00405
01: Masters Pharmaceutical case with the
02: executive committee, correct?
03: A. Yes.
04: Q. And it's drafted by HDA's
05: inhouse counsel, Ms. Gallenagh?
06: MR. WEINSTEIN: Objection to
07: form. Foundation.
08: THE WITNESS: Yeah, I don't
09: know if this was done by inhouse
10: counsel or outside OFW.
11: BY MR. PIFKO:
12: Q. Well, it's -- it says --
13: it's got her name on it here. Do I have
14: that correct?
15: A. Her name's on the e-mail.
16: Q. Well, but it says from John
17: Gray and Ms. Gallenagh.
18: A. Right.
19: Q. Do you see that?
20: A. Right, but I don't know who
21: drafted the -- the -- this document. I
22: don't know if that was done by inhouse or
23: outside counsel.
24: Q. Ms. Gallenagh is the same

p. 00405

00404
01: THE WITNESS: Again, I think
02: at the time I probably was aware
03: that that was the resolution of
04: the case.
05: BY MR. PIFKO:
06: Q. Okay.
07: (Document marked for
08: identification as Exhibit
09: HDA-Kelly-47.)
10: BY MR. PIFKO:
11: Q. I'm handing you what's
12: marked as Exhibit 47.
13: For the record, Exhibit 47
14: is an e-mail from John Gray dated
15: November 19th, 2015. The subject is
16: "Masters suit, draft amicus outline - for
17: your consideration." It's Bates-labeled
18: HDA_MDL_000219211 through 219213.
19: Take a moment to review it.
20: And let me know when you're done.
21: A. Okay.
22: Q. In Exhibit 47, John Gray is
23: sharing an outline of a draft amicus
24: brief or a draft amicus outline for the

p. 00404

00406
01: counsel that's here today at the
02: deposition?
03: A. That's correct.
04: Q. So this outline and summary
05: memo was provided to HDA's executive
06: committee -- committee members on
07: November 19, 2015, correct?
08: A. Yes.
09: Q. There was a request that
10: people consider this and provide input on
11: whether to pursue it, correct?
12: A. That's correct.
13: (Document marked for
14: identification as Exhibit
15: HDA-Kelly-48.)
16: BY MR. PIFKO:
17: Q. I'm handing you what's
18: marked as Exhibit 48. Take a minute to
19: review Exhibit 48. For the record,
20: Exhibit 48 is a two-page document
21: Bates-labeled HDA_MDL_000215966 through
22: 67.
23: It's dated from
24: January 2016, and the subject is "Action

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00407

01: requested - HDMA Masters amicus brief."
02: Let me know when you're
03: ready.
04: A. Okay.
05: Q. So in this document,
06: Exhibit 48, John Gray is again e-mailing
07: the executive committee and asking for
08: their approval to move forward with the
09: drafting of the amicus brief in the
10: Masters case, correct?
11: A. That's correct.
12: Q. And he notes that they're
13: going to hire someone from Latham &
14: Watkins, and they estimate the cost is
15: going to be about \$150,000, correct?
16: A. Yes. That's what this
17: states.
18: Q. Okay. And he says that he
19: recommends the executive committee
20: approve based on the following and
21: provides five bullet points describing
22: why Mr. Gray believes that the members
23: should approve the proceeding with
24: drafting and ultimately filing the brief,

p. 00407

00409

01: Q. I'm handing you what's
02: marked as Exhibit 49. Exhibit 49 is a
03: document Bates-labeled HDA_MDL_000162206
04: through 162256. It's an e-mail from you
05: dated April 5, 2016, to Ruth Miller.
06: Subject is "Amicus brief filed in Masters
07: case." It attaches the brief and a
08: consent motion. Let me know when you're
09: done.
10: A. I agree that's what it
11: includes.
12: Q. Okay. That's -- so you say
13: here on the first -- well, first -- this
14: is the final version of the brief that
15: was filed, correct?
16: A. To the best of my knowledge,
17: yes.
18: Q. And you're sharing this with
19: Ruth Miller?
20: A. Yes.
21: Q. Who is that?
22: A. Ruth Miller at the time was
23: in our regulatory affairs department. I
24: believe she was a senior director.

p. 00409

00408

01: correct?
02: A. Yes.
03: Q. And we see here on top of
04: the e-mail that AmerisourceBergen
05: approved that course of action, correct?
06: A. Yes.
07: Q. Do you know if the other
08: members approved the filing of the brief?
09: MR. WEINSTEIN: Objection to
10: form.
11: THE WITNESS: I don't know.
12: I know -- I think that the brief
13: was filed, so I'd imagine that
14: they did approve the filing of the
15: brief.
16: BY MR. PIFKO:
17: Q. Again, because they wouldn't
18: file a brief without approval of the
19: executive committee members, correct?
20: A. That's correct.
21: (Document marked for
22: identification as Exhibit
23: HDA-Kelly-49.)
24: BY MR. PIFKO:

p. 00408

00410

01: Q. And what was her role in the
02: regulatory affairs department?
03: A. Her role was primarily in
04: the DEA-related regulatory affairs
05: issues.
06: Q. What specifically does she
07: do?
08: A. She would basically review
09: various regulatory documents and
10: interactions with the DEA.
11: Q. For what purpose?
12: MR. WEINSTEIN: Objection to
13: form.
14: THE WITNESS: To represent
15: HDA's interest in front of the
16: agency.
17: BY MR. PIFKO:
18: Q. You say here, "Long story
19: short, our members felt it was an
20: important opportunity to weigh in as
21: dispassionately as possible with the
22: Court on some of the ambiguities that
23: Masters referenced in their pleadings as
24: well as some of the points that the

p. 00410
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00411

01: administrative law judge addressed in her
02: recommendations to overturn the
03: suspension order."
04: Do you see that?
05: A. I do.
06: Q. Were you part of discussions
07: with the members about this brief?
08: MR. WEINSTEIN: Objection to
09: form.
10: THE WITNESS: Not the
11: details of the brief itself. That
12: was handled by Latham & Watkins.
13: But I was aware that the brief was
14: being crafted and was going to be
15: submitted.
16: BY MR. PIFKO:
17: Q. And the members shared their
18: views on the strategy with you, such that
19: you could provide it here to Ms. Miller?
20: MR. WEINSTEIN: Objection to
21: form. Foundation. Scope.
22: THE WITNESS: The members of
23: this instance would have probably
24: been involved to the legal

p. 00411

00413

01: amicus brief that was filed in the West
02: Virginia Supreme Court of Appeals. It's
03: Bates-labeled HDA_MDL_000212579 through
04: 212616.
05: A. Okay.
06: Q. Are you aware that HDMA
07: filed an amicus brief in the West
08: Virginia State Court litigation against
09: the distributors?
10: A. I am.
11: Q. And did the executive
12: committee authorize the filing of that
13: brief?
14: A. I would think that they
15: would have, yes.
16: Q. Do you have any reason to
17: believe that they wouldn't have supported
18: it?
19: A. No.
20: MS. WICHT: Objection to
21: form.
22: BY MR. PIFKO:
23: Q. I'm going to turn your
24: attention back to Exhibit 1, the subpoena

p. 00413

00412

01: committee, HDA's legal committee
02: and handled there. So I think
03: they probably did provide feedback
04: to the strategy as it was moving
05: forward.
06: BY MR. PIFKO:
07: Q. What's your understanding of
08: what the ambiguities were that Masters
09: referenced in their pleadings?
10: MR. WEINSTEIN: Objection to
11: form. Scope. Foundation. And
12: calls for a legal conclusion.
13: THE WITNESS: Again, I think
14: some of the ambiguities had to do
15: with the authority that DEA
16: referenced in their action against
17: Masters.
18: (Document marked for
19: identification as Exhibit
20: HDA-Kelly-50.)
21: BY MR. PIFKO:
22: Q. I'm handing you what's
23: marked Exhibit 50. For the record,
24: Exhibit 50 is an e-mail attaching another

p. 00412

00414

01: with the topics. Are you there?
02: A. I am.
03: Q. Okay. Topic Number 3 is
04: your lobbying activities related to the
05: manufacture, marketing, advertising and
06: distribution of opioids or opioid
07: products.
08: Do you see that?
09: A. I do.
10: Q. Do you understand yourself
11: to be -- have been designated to talk
12: about that topic here today?
13: A. I do.
14: Q. We talked about Topic 4
15: already.
16: Topic Number 5: Your
17: advocacy or legal support for any
18: defendant, including but not limited to,
19: amicus curiae briefs or any -- or other
20: legal documents prepared by you in
21: support of any defendant.
22: Do you see that?
23: A. I do.
24: Q. Do you understand yourself

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00415

01: to be designated to talk on that topic
02: today?
03: A. I do.
04: Q. Topic Number 6: The nature,
05: scope and identity of any conferences,
06: seminars or webinars you have sponsored,
07: promoted or organized where the duty to
08: prevent diversion and identify and report
09: suspicious orders was included among the
10: topics of discussion.
11: Do you see that?
12: A. I do.
13: Q. Do you understand yourself
14: to be designated to talk on that topic
15: today?
16: A. I do.
17: Q. Topic Number 7:
18: Communications with the DEA or any state
19: or federal government agency regarding
20: the diversion or suspicious orders of
21: opioids or opioid products, including but
22: not limited to, the attendance,
23: participation in, presentations given by
24: the DEA at your conferences, seminars, or

p. 00415

00417

01: A. I do.
02: Q. Do you understand yourself
03: to be designated to talk on that topic
04: today?
05: A. I do.
06: Q. Topic Number 13: The scope
07: and nature of any discussions of any
08: council, committee, task force, or
09: working group of the HDA concerning
10: diversion of controlled substances.
11: Do you see that?
12: A. I do.
13: Q. Do you understand yourself
14: to be designated to talk on that topic
15: today?
16: A. I do.
17: Q. What did you do to prepare
18: to testify on those topics?
19: A. I met with counsel several
20: days in the last couple days and then
21: previously when we thought this was going
22: to be scheduled earlier, or later in
23: 2018. So probably four or five meetings
24: with counsel and staff.

p. 00417

00416

01: webinars regarding advice, direction,
02: guidance or instruction regarding the
03: duty to prevent diversion and identify
04: and report suspicious orders.
05: Do you understand yourself
06: to be designated to talk on that topic
07: today?
08: A. I do.
09: Q. Topic Number 8: Any
10: communications efforts, activities,
11: initiatives or work performed by you
12: regarding quotas set by the DEA,
13: including increases to or maintenance of
14: the quotas.
15: Do you understand yourself
16: to be designated to talk on that topic
17: today?
18: A. Yes.
19: Q. The scope -- Topic
20: Number 12: The scope and nature of any
21: discussions of any council, committee,
22: task force or working group of the HDA
23: concerning opioids.
24: Do you see that?

p. 00416

00418

01: Q. Okay. I was going to ask
02: you. Besides counsel, did you meet with
03: any staff members?
04: A. I did. I met with Anita
05: Ducca primarily to understand the period
06: of time I was not at HDA.
07: Q. And did she provide any
08: documents to you?
09: A. Other than the documents
10: that were produced.
11: Q. So she provided documents to
12: you that were produced?
13: MR. WEINSTEIN: Objection to
14: form.
15: THE WITNESS: No. Counsel
16: provided the documents.
17: BY MR. PIFKO:
18: Q. Okay. So when you
19: understood you were going to be
20: designated to come speak for the HDA at
21: this deposition, counsel provided you
22: with documents that had been produced in
23: the litigation?
24: A. That's correct.

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00419

01: Q. Okay. And when you met with
02: Ms. Ducca, did we go over any of those
03: documents?
04: A. We did.
05: Q. Okay. Did you review the
06: documents on your own time without
07: anybody?
08: A. I did not.
09: Q. Okay. Who else besides
10: Ms. Ducca from the staff did you meet
11: with?
12: A. Our general counsel
13: participated in the meetings as well.
14: Q. Okay. Anyone else?
15: A. No.
16: Q. About how many hours did you
17: meet with Ms. Ducca?
18: A. Over the course, probably
19: eight -- between eight and ten hours.
20: Q. And you felt, based on those
21: discussions and the review of documents,
22: that you had adequate understanding to
23: testify on those topics I just read to
24: you?

p. 00419

00420

01: A. I do.
02: MR. PIFKO: Okay. We'll
03: take a break.
04: THE VIDEOGRAPHER: The time
05: is 5:09 p.m. We are off the
06: record.
07: (Short break.)
08: THE VIDEOGRAPHER: The time
09: is 5:25 p.m. We are back on the
10: record.
11: (Document marked for
12: identification as Exhibit
13: HDA-Kelly-51.)
14: BY MR. PIFKO:
15: Q. Handing you what's marked as
16: Exhibit 51.
17: And while you are looking --
18: go ahead and take your time to look at
19: that, but then I also want you to pull
20: out Exhibit 11 which goes with
21: Exhibit 51.
22: For the record, Exhibit 51
23: is a three-page document Bates-labeled
24: CAH_MDL2804_02201918 through 1920.

p. 00420

00421

01: A. 11?
02: Q. Yeah.
03: A. Document 11?
04: Q. Okay. You ready?
05: A. Yes.
06: Q. So you recall, when I showed
07: you Document 11 and I asked you if you
08: had an understanding about the date of
09: when the National Wholesale Druggists'
10: Association suspicious order monitoring
11: system, which is Exhibit 11, what the
12: date of that document was, do you recall
13: that discussion?
14: A. I recall that discussion,
15: yes.
16: Q. Okay. Well, Exhibit 51 is a
17: series of letters from the DEA concerning
18: the National Wholesale Druggists'
19: Association's suspicious order monitoring
20: system. And if you see, the first page
21: of Exhibit 51 is stamped April 27, 1984.
22: Do you see that?
23: A. I do.
24: Q. Does that refresh your

p. 00421

00422

01: recollection that Exhibit 11 is from
02: approximately in the early '80s?
03: MR. WEINSTEIN: Objection to
04: form, foundation, scope.
05: THE WITNESS: I will --
06: again, I have not seen either of
07: these documents. I will take it
08: at face value that that was when
09: this document was prepared.
10: BY MR. PIFKO:
11: Q. Okay. Well, Exhibit 51 is a
12: letter from Thomas Gitchel, acting chief
13: diversion operations section of the DEA,
14: correct?
15: A. Yes.
16: Q. And it's dated April 27,
17: 1984, correct?
18: A. Yes.
19: Q. And it's to Ronald J.
20: Streck, vice president of government
21: affairs, National Wholesale Druggists'
22: Association.
23: That's a predecessor entity
24: of HDA, correct?

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00423

01: A. That's correct.
02: Q. Do you know who Mr. Streck
03: is?
04: A. Mr. Streck became at one
05: point the CEO of the NWDA.
06: Q. Okay. Do you know around
07: the time that was?
08: A. I do not know when he --
09: Mr. Gray did succeed him as the CEO.
10: Q. Okay. Mr. Gray was
11: immediately after him?
12: A. Immediately after him, yes.
13: Q. Okay. So this document
14: says, the second full paragraph, "The
15: NWDA's draft format for suspicious order
16: monitoring system provides an excellent
17: framework for distributor" --
18: "distributor registrants to design and
19: operate a system to disclose to
20: registrants suspicious orders of
21: controlled substances."
22: Do you see that?
23: A. I do.
24: Q. And it says, "Draft format

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00425

01: form. Foundation. Scope.
02: THE WITNESS: No reason to
03: dispute that they received a pen
04: and ink draft marked-up version.
05: BY MR. PIFKO:
06: Q. And this letter from DEA,
07: correct?
08: MR. WEINSTEIN: Same
09: objections.
10: THE WITNESS: No reason to
11: dispute that.
12: BY MR. PIFKO:
13: Q. Based on your understanding
14: of the HDA and as a designee under Rule
15: 30(b)(6), do you believe this would have
16: been provided to HDA's members?
17: MR. WEINSTEIN: Objection to
18: form, foundation, and scope.
19: THE WITNESS: Again, I don't
20: know what capabilities were back
21: in 1984. I would imagine it was
22: reported at some point to HDA
23: members.
24: BY MR. PIFKO:

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00424

01: for a suspicious order monitoring
02: system." And Exhibit 11 says,
03: "Suspicious order monitoring system,"
04: correct?
05: A. It does.
06: Q. Okay. Then on the bottom of
07: that same paragraph, Mr. Gitchel says in
08: the letter to Mr. Streck, "As previously
09: discussed, an after-the-fact computer
10: printout of sales data does not relieve a
11: registrant of its responsibility to
12: report excessive or suspicious orders
13: when discovered."
14: Do you see that?
15: A. I do.
16: Q. And then he says, "I'm
17: enclosing a copy of your draft with my
18: pen and ink changes."
19: Do you see that?
20: A. I do.
21: Q. Do you agree -- any reason
22: to dispute that the NWDA received this
23: document?
24: MR. WEINSTEIN: Objection to

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00426

01: Q. Okay. In the first
02: paragraph --
03: A. Or NWDA members.
04: Q. In the first paragraph he
05: says, "I want to thank" -- "I want to
06: take this opportunity to thank you,
07: Mr. Streck, and then Mr. David Prins,
08: from Twin City Wholesale, and Mr. Robert
09: Bone from Bergen Brunswig for meeting
10: with David Walkup and me on April 13,
11: 1984."
12: Do you see that?
13: A. I do.
14: Q. So based on this, it appears
15: some of the members in addition to
16: Mr. Streck met with the DEA about the
17: suspicious order monitoring system,
18: correct?
19: A. It would appear so, yes.
20: Q. Then the third page of
21: Exhibit 51 is another letter to
22: Mr. Streck from Thomas Gitchel.
23: Do you see that?
24: A. I do.

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00427

01: Q. And it appears to be dated
02: May 16, 1984.
03: Do you see that?
04: A. I do.
05: Q. In the letter from
06: Mr. Gitchel, he says at the bottom of the
07: first full paragraph, "However, I want to
08: make it clear that the submission of
09: monthly printout of after-the-fact sales
10: will not relieve a registrant from the
11: responsibility of reporting excessive or
12: suspicious orders. DEA has interpreted
13: orders to mean prior to shipment."
14: Do you see that?
15: A. I do.
16: Q. And that's consistent with
17: the language that we discussed on Page
18: seven of Exhibit 11 where it says, "DEA
19: has interpreted orders to mean prior to
20: shipment."
21: Do you see that?
22: A. I do.
23: Q. Do you agree that it's --
24: this DEA letter from 1984 is consistent

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00429

01: THE WITNESS: Most -- yes,
02: as most trade associations do, on
03: behalf of their members.
04: MR. PIFKO: Okay. We're
05: going to hold the deposition of
06: HDA open, given some of the
07: prior -- the deposition of Mr. Fri
08: and some issues we can meet and
09: confer about. We don't have to
10: waste everyone's time.
11: I'm going to turn it over to
12: the Tennessee counsel.
13: MR. WEINSTEIN: We can speak
14: outside. I had no notice, and I
15: do not agree that Tennessee can
16: ask questions. Not after seven
17: hours.
18: MR. STEWART: It's properly
19: noticed.
20: MR. WEINSTEIN: It was not
21: noticed to me. I'm not having my
22: witness testify after seven hours.
23: THE VIDEOGRAPHER: So we're
24: going to go off the record

p. 00429

00428

01: with that language in the NWDA's
02: suspicious order monitoring system?
03: MR. WEINSTEIN: Objection to
04: form, foundation, and scope.
05: THE WITNESS: It appears to
06: be the same statement, yes.
07: BY MR. PIFKO:
08: Q. Do you believe that this May
09: 16th, 1984 letter would have been shared
10: with the NWDA's members?
11: MR. WEINSTEIN: Objection to
12: form, foundation, and scope.
13: THE WITNESS: Again, I can't
14: say for certain. I would imagine
15: that it was. As correspondence
16: like this would technically be
17: shared with the membership.
18: BY MR. PIFKO:
19: Q. And again, because HDA and
20: its predecessor entities would act on
21: behalf of the members, not for its own
22: interest, correct?
23: MR. WEINSTEIN: Objection to
24: form, foundation, and scope.

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00430

01: obviously. The time is 5:34 p.m.
02: We're going off the record.
03: (Short break.)
04: THE VIDEOGRAPHER: The time
05: is 5:35 p.m. We're back on the
06: record.
07: MR. STEWART: I'll let you
08: speak.
09: My understanding is that
10: after we've been sitting here for
11: hours and hours, and obviously the
12: expectation was that, as with the
13: deposition earlier in the week,
14: that we would take our two hours
15: of testimony. I'm being told that
16: you are not going to permit the
17: witness to testify today; is that
18: correct?
19: MR. WEINSTEIN: That's
20: correct, Mike. So let me explain.
21: On Tuesday in the deposition
22: of Mr. Fri, you approached me,
23: identified who you were. That was
24: the first that I had ever heard of

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00431

01: anything relating to Tennessee. I
02: had not received any notice of a
03: deposition with respect to
04: Mr. Fri.
05: You then e-mailed it to me
06: on the spot. I said that's --
07: this is the first I'm hearing of
08: it. You said, well, we'd like to
09: ask Mr. Fri an hour's worth of
10: questions, and if you'll agree to
11: that, then in exchange we'll agree
12: not to try to depose him in the
13: Tennessee matter.
14: The plaintiffs' deposition
15: of Mr. Fri had only taken a couple
16: of hours or so, he was already
17: there. I said, under those
18: circumstances I'll agree.
19: I never received any notice
20: for Mr. Kelly to give deposition
21: today in the Tennessee matter. In
22: fact, when I spoke to you on
23: Tuesday, you said, well, we can
24: either ask our questions today or

p. 00431

00433

01: deal on Tuesday, I never offered
02: to do that testimony on Friday,
03: because obviously that was a
04: different witness.
05: Now, I understood today we'd
06: be doing the same thing, whereby
07: in exchange for not bringing this
08: witness for a full deposition
09: under Tennessee law, that we would
10: take two hours of testimony today.
11: We noticed this deposition
12: the exact same way we noticed the
13: other deposition.
14: And obviously, unlike
15: Tuesday, I mean, you had notice
16: that we were coming. We've also
17: been sitting here for eight hours.
18: This is the first time that I've
19: heard of this.
20: So to me, what I would do if
21: I were you is, to allow your
22: witness to go forward and testify.
23: I'm happy to make the same
24: agreement whereby if he'll testify

p. 00433

00432

01: we can ask our questions Friday,
02: whatever you want.
03: So I had no -- nor did I get
04: any notice that you were going to
05: try to ask Mr. Kelly any
06: questions. He's been testifying
07: for seven hours. So I'm not
08: agreeing to have Mr. Kelly
09: testify.
10: We also reserve all rights
11: as we did on Tuesday as to whether
12: Tennessee is entitled to
13: testimony, given my understanding
14: that your investigation relates to
15: manufacturers, which Mr. Kelly and
16: HDA have very limited testimony to
17: give regarding. So that's my
18: position.
19: MR. STEWART: That's fine,
20: but the one area we have a factual
21: disagreement, I'm sure in good
22: faith, is that I think if you look
23: back on our statements to each
24: other, where we articulated our

p. 00432

00434

01: for two hours, we won't bring him
02: back in this litigation.
03: Obviously, if not, I believe
04: this is properly noticed. It's
05: potentially sanctionable to not
06: allow him to testify.
07: Also, we may well simply
08: subpoena him for a Tennessee
09: deposition under Tennessee rules.
10: And if we do so, of course, I want
11: to make sure this is clear, under
12: the Tennessee rules, a deposition
13: has no time and it continues from
14: day-to-day. And we'll just, if we
15: choose to subpoena him, based on
16: this failure today, obviously we
17: won't restrict our time in any
18: way.
19: To me, it would seem to make
20: more sense since we are all
21: sitting here just to go ahead and
22: take the deposition. But
23: obviously I can't force you to
24: produce your witness other than to

p. 00434

00435

01: provide you a notice which we have
02: done.
03: MR. WEINSTEIN: You actually
04: haven't, Mike. I don't have that
05: notice.
06: Did you -- are you telling
07: me that you sent me that notice?
08: Because you have not.
09: MR. STEWART: Well, I can
10: tell you -- I'm speaking obviously
11: for my law firm. I don't handle
12: that notice --
13: MR. WEINSTEIN: Yeah.
14: MR. STEWART: -- but I just
15: spoke to the person who provides
16: the notices, whose noticed at
17: least 45 depositions in the opioid
18: litigation. We've never had a
19: problem like this before today.
20: So I think when I tell you
21: that our firm has properly noticed
22: this, I think it's unlikely that
23: after so many depositions with no
24: hiccoughs and no difficulties,

p. 00435

00436

01: that for some reason this
02: deposition proved to be a problem.
03: MR. WEINSTEIN: Mike, we are
04: a third party. Never received
05: your first notice until you handed
06: it to me by e-mail when we were
07: standing out in the hall on
08: Tuesday. Never received a notice
09: with respect to Mr. Kelly. So
10: we're not changing our position.
11: MR. STEWART: I understand.
12: Well, I think -- I think that
13: problem that puts us -- gives us
14: is that then our choice, I
15: suppose, is to seek sanctions in
16: our litigation.
17: Or, and as an alternative,
18: or as coupled with that, to just
19: subpoena your witness and come
20: back for a deposition.
21: MR. WEINSTEIN: Mike --
22: MR. STEWART: I think the
23: notion that this testimony is not
24: relevant to the Tennessee

p. 00436

00437

01: litigation and to the opioid
02: crisis in Tennessee has been amply
03: disproven by the testimony that's
04: already been taken today.
05: But I don't -- it doesn't
06: sound like we're going to reach an
07: agreement --
08: MR. WEINSTEIN: Correct.
09: MR. STEWART: -- so I've
10: told you what we're planning to
11: do. I've informed you.
12: And it sounds like with that
13: information you're continuing to
14: hold to your position of not
15: allowing us to take questions
16: today; is that correct?
17: MR. WEINSTEIN: That's
18: correct.
19: MR. STEWART: Okay. That's
20: unfortunate. And obviously we'll
21: both just have to take the steps
22: to do what we have to for our
23: clients.
24: MR. WEINSTEIN: That's

p. 00437

00438

01: correct.
02: THE VIDEOGRAPHER: Any other
03: statements on the record? Is that
04: it for today?
05: MS. MACKAY: I have a few
06: questions.
07: MR. WEINSTEIN: Go ahead.
08: - - -
09: EXAMINATION
10: - - -
11: BY MS. MACKAY:
12: Q. My name is Melanie Mackay,
13: I'm from Dechert. I'm one of the
14: attorneys who represents Purdue. I just
15: have a few questions for you. And I'm
16: sorry, they are on my computer, so if I'm
17: looking at my computer screen I'm not
18: ignoring you. I'm just looking at my
19: questions?
20: A. Okay.
21: Q. So Purdue is a manufacturer.
22: And I believe you said earlier that
23: Purdue is an affiliate member; is that
24: correct?

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00439

01: A. I believe so, yes.
02: Q. And can you describe what it
03: means to be an affiliate member?
04: A. So affiliate members at HDA
05: are manufacturers who our member
06: companies are trading partners with.
07: They are not afforded the same membership
08: status as the core members who are the
09: distributor members. They are not
10: allowed to participate in committees.
11: They can't be on the board. They are
12: welcome to participate in HDA meetings
13: and external events if they register for
14: those. But as far as communication
15: internal, particularly in government
16: affairs, we deal strictly with the HDA
17: core members.
18: Q. Plaintiff's counsel today
19: often used the term "HDA members." And I
20: just want to clarify how you understand
21: that term.
22: Unless counsel specifically
23: referred to manufacturers, did you
24: understand the term "members" to mean

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00441

01: convene interaction. We just do an
02: update twice a year.
03: Q. Did Purdue or any other
04: manufacturer ever serve on the regulatory
05: affairs committee?
06: A. No.
07: Q. And I believe you testified
08: earlier that the -- the regulatory
09: affairs committee created the -- HDA's
10: industry compliance guidelines; is that
11: correct?
12: A. That's -- that's correct.
13: Q. The industry compliance
14: guidelines are guidelines for
15: distributors; is that right?
16: A. That's correct.
17: Q. They are not meant to be
18: implemented by manufacturers?
19: A. That is correct.
20: Q. You briefly testified about
21: the drug diversion DEA strategy task
22: force. Do you recall that?
23: A. I do.
24: Q. Did manufacturer members

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00440

01: core members?
02: A. Yes. I believe we -- did we
03: not stipulate to that early on? Yes,
04: that's what I'm -- yes, that was my
05: understanding.
06: Q. Okay. And again, the core
07: members are distributors?
08: A. That's correct.
09: Q. You may have already
10: answered this question for me. But are
11: manufacturers members of any committees
12: or other groups that fall under the
13: umbrella of the government affairs
14: department?
15: A. The only -- the only
16: committee within HDA that manufacturers
17: are allowed to participate in is there's
18: a government advisory -- manufacturers
19: government advisory committee that meets
20: twice a year. And that is essentially an
21: opportunity for us to provide an update
22: on HDA government affairs activities.
23: But that does not meet, it
24: does not meet in person. We do not

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00442

01: serve on that task force?
02: A. They did not.
03: Q. Switching gears back to the
04: industry compliance guidelines, did
05: manufacturers participate in the
06: development and drafting of the industry
07: compliance guidelines?
08: A. They did not.
09: Q. Did the Pain Care Forum
10: participate in the development and
11: drafting of the industry compliance
12: guidelines?
13: A. They did not.
14: MS. MACKAY: That's the only
15: questions I have for you. Thank
16: you.
17: MR. WEINSTEIN: I'd like to
18: designate the transcript as
19: confidential, please.
20: THE VIDEOGRAPHER: Anybody
21: else? Okay. Do you want to close
22: the record?
23: The time is 5:45 p.m., May
24: 10, 2019. We are going off the

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00443
01: record.
02: This ends this videotape
03: session.
04: (Excused.)
05: (Deposition concluded at
06: approximately 5:45 p.m.)
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00445
01: INSTRUCTIONS TO WITNESS
02:
03: Please read your deposition
04: over carefully and make any necessary
05: corrections. You should state the reason
06: in the appropriate space on the errata
07: sheet for any corrections that are made.
08: After doing so, please sign
09: the errata sheet and date it.
10: You are signing same subject
11: to the changes you have noted on the
12: errata sheet, which will be attached to
13: your deposition.
14: It is imperative that you
15: return the original errata sheet to the
16: deposing attorney within thirty (30) days
17: of receipt of the deposition transcript
18: by you. If you fail to do so, the
19: deposition transcript may be deemed to be
20: accurate and may be used in court.
21:
22:
23:
24:

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00444
01:
02: CERTIFICATE
03:
04:
05: I HEREBY CERTIFY that the
witness was duly sworn by me and that the
06: deposition is a true record of the
testimony given by the witness.
07:
It was requested before
08: completion of the deposition that the
witness, PATRICK KELLY, have the
09: opportunity to read and sign the
deposition transcript.
10:
11:
12: _____
MICHELLE L. GRAY,
13: A Registered Professional
Reporter, Certified Shorthand
14: Reporter, Certified Realtime
Reporter and Notary Public
15: Dated: May 13, 2019
16:
17:
18: (The foregoing certification
19: of this transcript does not apply to any
20: reproduction of the same by any means,
21: unless under the direct control and/or
22: supervision of the certifying reporter.)
23:
24:

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00446
01: - - - - -
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04: PAGE LINE CHANGE
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23: _____
24: REASON: _____

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00447
01:
02: ACKNOWLEDGMENT OF DEPONENT
03:
04: I, _____, do
05: hereby certify that I have read the
06: foregoing pages, 1 - 448, and that the
07: same is a correct transcription of the
08: answers given by me to the questions
09: therein propounded, except for the
10: corrections or changes in form or
11: substance, if any, noted in the attached
12: Errata Sheet.
13:
14:
15:
16: _____
17: PATRICK KELLY DATE
18:
19:
20: Subscribed and sworn
 to before me this
21: ____ day of _____, 20____.
22: My commission expires: _____
23: _____
24: Notary Public

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00448
01: LAWYER'S NOTES
02: PAGE LINE
03: _____
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